

# **EXHIBIT A**

**MISSOURI CIRCUIT COURT  
TWENTY-SECOND JUDICIAL CIRCUIT, ST. LOUIS CITY**

<b>RAY COUNTY, MISSOURI</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>V.</b>	)	Case No.
	)	<b>Division No.</b>
<b>ALLERGAN PLC</b>	)	
<b>Serve: Corporate Creations Network Inc.</b>	)	<b>JURY TRIAL DEMANDED</b>
<b>12747 Olive Boulevard, Suite 300</b>	)	
<b>St. Louis, MO 63141</b>	)	
	)	
<b>ACTAVIS PLC</b>	)	
<b>Serve: 5 Giralda Farms</b>	)	
<b>Madison, NJ 07940</b>	)	
	)	
<b>ACTAVIS, INC.</b>	)	
<b>Serve: 5 Giralda Farms</b>	)	
<b>Madison, NJ 07940</b>	)	
	)	
<b>WATSON PHARMACEUTICALS, INC.</b>	)	
<b>n/k/a ACTAVIS, INC.</b>	)	
<b>Serve: Corporate Creations Network Inc.</b>	)	
<b>12747 Olive Boulevard, Suite 300</b>	)	
<b>St. Louis, MO 63141</b>	)	
	)	
<b>WATSON LABORATORIES, INC.</b>	)	
<b>Serve: Steve Anderson</b>	)	
<b>29908 E. Old 50 Highway</b>	)	
<b>Lee's Summit, MO 64086</b>	)	
	)	
<b>ACTAVIS LLC</b>	)	
<b>Serve: 5 Giralda Farms</b>	)	
<b>Madison, NJ 07940</b>	)	
	)	
<b>ACTAVIS PHARMA, INC. f/k/a</b>	)	
<b>WATSON PHARMA, INC.</b>	)	
<b>Serve: Corporate Creations Network Inc.</b>	)	
<b>12747 Olive Boulevard, Suite 300</b>	)	
<b>St. Louis, MO 63141</b>	)	
	)	

TEVA PHARMACEUTICAL )  
INDUSTRIES, LTD. )  
Serve: 1090 Horsham Road )  
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Attn: Deborah Griffin )  
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TEVA PHARMACEUTICALS USA, )  
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CEPHALON, INC. )  
Serve: Corporate Creations Network Inc. )  
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ENDO HEALTH SOLUTIONS INC. )  
Serve: The Corporation Trust Company )  
Corporation Trust Center )  
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Wilmington, DE 19801 )  
 )  
ENDO PHARMACEUTICALS, INC. )  
Serve: The Corporation Trust Company )  
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PAR PHARMACEUTICAL, INC. )  
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JANSSEN PHARMACEUTICALS, INC. )  
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120 South Central Avenue )  
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 )  
ORTHO-MCNEIL-JANSSEN )  
PHARMACEUTICALS, INC. n/k/a )  
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JANSSEN PHARMACEUTICA, INC. )  
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JOHNSON & JOHNSON )  
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SPECGX LLC )  
Serve: C T Corporation System )  
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NOVARTIS PHARMACEUTICALS )  
CORPORATION f/k/a SANDOZ, INC. )  
Serve: CSC-Lawyers Incorporating )  
Service Company )  
221 Bolivar Street )  
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 )  
MYLAN N.V., )  
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 )  
MYLAN PHARMACEUTICALS, INC. )  
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Charleston, WV 25311 )  
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MYLAN INSTITUTIONAL, INC. )  
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208 So Lasalle Street, Suite 814 )  
Chicago, IL 60604 )  
 )  
HOSPIRA, INC. )  
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120 South Central Avenue )  
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HIKMA PHARMACEUTICALS USA, )  
INC. f/k/a WEST-WARD )  
PHARMACEUTICALS CORP. )  
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JOHN KAPOOR, an individual )  
Serve: 6610 N 29<sup>th</sup> Place )  
Phoenix, AZ 85016 )  
 )  
MICHAEL BABICH, an individual )  
Serve: 18391 North 97<sup>th</sup> Place )  
Scottsdale, AZ 85255 )  
 )

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CORPORATION )  
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AMERISOURCEBERGEN DRUG )  
CORPORATION )  
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CARDINAL HEALTH, INC. )  
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4400 Easton Commons Way, Suite 125 )  
Columbus, OH 43219 )  
 )  
CARDINAL HEALTH 5, LLC )  
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CARDINAL HEALTH 100, INC. )  
Serve: C T Corporation System )  
120 South Central Avenue )  
Clayton, MO 63105 )  
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CARDINAL HEALTH 108, LLC )  
Serve: C T Corporation System )  
120 South Central Avenue, Suite 400 )  
Clayton, MO 63105 )  
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CARDINAL HEALTH 110, LLC )  
Serve: C T Corporation System )  
120 South Central Avenue )  
Clayton, MO 63105 )  
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CARDINAL HEALTH 113, LLC )  
Serve: C T Corporation System )  
120 South Central Avenue )  
Clayton, MO 63105 )  
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**CARDINAL HEALTH 122, LLC** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
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**CARDINAL HEALTH 132, LLC;** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
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**CARDINAL HEALTH 200, LLC** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
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**CARDINAL HEALTH 201, INC.** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
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**CARDINAL HEALTH 414, LLC** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
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**CARDINAL HEALTH PHARMACY** )  
**SERVICES, LLC** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
 )  
**WALMART INC. f/k/a WAL-MART** )  
**STORES, INC.** )  
Serve: C T Corporation System )  
**120 South Central Avenue** )  
**Clayton, MO 63105** )  
 )  
**PHARMACY BUYING ASSOCIATION,** )  
**INC.** )  
Serve: Nick Smock )  
**6300 Enterprise Road** )  
**Kansas City, MO 64120** )  
 )

and DOES 1 through 1000, )  
Defendants. )

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**PETITION**

Plaintiff Ray County, Missouri (“Plaintiff” or “Ray County”), for its Petition against Defendants ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; PAR PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; MALLINCKRODT, PLC; MALLINCKRODT LLC; SPECGX LLC; NOVARTIS PHARMACEUTICALS CORPORATION f/k/a SANDOZ, INC.; MYLAN N.V.; MYLAN PHARMACEUTICALS, INC.; MYLAN INSTITUTIONAL INC.; HOSPIRA, INC.; HIKMA PHARMACEUTICALS USA INC. f/k/a WEST-WARD PHARMACEUTICALS CORP.; JOHN KAPOOR; MICHAEL BABICH; AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; CARDINAL HEALTH 5, LLC; CARDINAL HEALTH 100, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 113, LLC; CARDINAL HEALTH 122, LLC; CARDINAL HEALTH 132, LLC; CARDINAL HEALTH 200, LLC; CARDINAL HEALTH 201, INC.; CARDINAL HEALTH 414, LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC;

WALMART INC. f/k/a WAL-MART STORES, INC.; PHARMACY BUYING ASSOCIATION, INC.; and DOES 1 through 1000, states and alleges as follows:

**I. INTRODUCTION**

1. Opiates<sup>1</sup> are killing people every day in this country and Missourians have not been spared. Each of the Defendants in this action engaged in an industry-wide effort to downplay the addictive and deadly potential effects of the misuse of prescription opioids. The opioid epidemic has hit every community in Missouri hard, including Ray County. Ray County brings this Petition seeking redress for the societal and financial damage it has suffered at the hands of those directly responsible for the crisis—the manufacturers and distributors of prescription opioids.

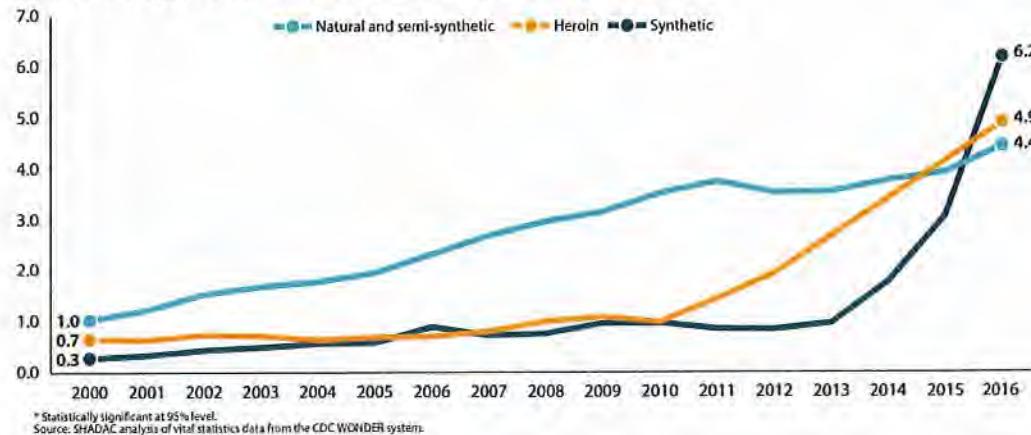
2. This case is about corporate greed. Simply stated, each of the Defendants put its desire for profits above the health and well-being of Ray County's residents. Ray County and its citizens have paid dearly as a result.

3. This case is not about taking away medically-necessary opioids from the patients who need them. Plaintiff does not ask the Court to decide whether opioids are clinically appropriate, nor does Plaintiff seek to blame the well-meaning healthcare providers and suppliers who prescribed opioids to their patients in good faith. Instead, Plaintiff only asks that this Court hold the Defendants accountable for the damage they caused to Ray County that Defendants were always in the best position to prevent.

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<sup>1</sup> The term “opiate” technically refers only to chemicals that occur naturally in the opium plant, including morphine, codeine, thebaine and papaverine. “Opioid,” by contrast, refers instead to compounds that have the same effect as opiates but do not occur naturally in the opium plant, such as heroin, oxycodone, hydrocodone, hydromorphone and oxymorphone (“semi-synthetic” opioids) as well as methadone, fentanyl, meperidine and tramadol (“synthetic” opioids).

Figure 1: U.S. Opioid Death Rates Per 100,000 People, 2000-2016



## A. The Manufacturer Defendants' Two-Part Scheme to Increase Opioid Sales

4. First, as part of a broader scheme to target municipalities in the United States where the elements most conducive to opioid addiction were prevalent, Defendants ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT, PLC; MALLINCKRODT LLC; SPECGX LLC; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; PAR PHARMACEUTICAL, INC.; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; NOVARTIS PHARMACEUTICALS CORPORATION f/k/a SANDOZ, INC.; MYLAN N.V.; MYLAN INSTITUTIONAL, INC.; MYLAN PHARMACEUTICALS, INC.; HOSPIRA, INC.; HIKMA PHARMACEUTICALS USA INC. f/k/a WEST-WARD

PHARMACEUTICALS CORP.; and the individual defendants JOHN KAPOOR; and MICHAEL BABICH (“the Manufacturer Defendants”), targeted the State of Missouri, including the residents of Ray County. The Manufacturer Defendants developed and engaged in a sophisticated, manipulative scheme designed to increase the number of opioid prescriptions written across the state, including in Ray County. Defendants’ scheme was particularly well-suited to Ray County, because Ray County is not only a rural community with limited access to a variety of health care resources and services that are generally offered in more populated counties, but is also home to economically and medically vulnerable populations that Defendants knew were uniquely predisposed to opioid addiction, including the elderly.

5. Second, the Manufacturer Defendants dramatically increased the number of opioid prescriptions in Ray County and across the country by (1) concealing the truth about the risk of addiction and death associated with long-term use of their products, and (2) pressuring their respective sales forces to deceive (even bribe) local prescribers to flood Missouri—and Ray County—with an abundance of opioids. In 2017, Missouri providers wrote 71.8 opioid prescriptions for every 100 persons compared to the U.S. average rate of 58.7 prescriptions for every 100 persons.<sup>2</sup>

**B. The Distributor Defendants Turned a Blind Eye to the Manufacturers’ Scheme**

6. Defendants AMERISOURCEBERGEN CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; CARDINAL HEALTH 5, LLC; CARDINAL HEALTH 100, INC.; CARDINAL HEALTH 108, LLC; CARDINAL HEALTH 110, LLC; CARDINAL HEALTH 113, LLC; CARDINAL HEALTH 122, LLC; CARDINAL HEALTH 132, LLC; CARDINAL

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<sup>2</sup> National Institutes of Health (“NIH”), National Institute on Drug Abuse, *Missouri Opioid Summary*, DrugAbuse.gov (Mar. 2019), <https://www.drugabuse.gov/opioid-summaries-by-state/missouri-opioid-summary>.

HEALTH 200, LLC; CARDINAL HEALTH 201, INC.; CARDINAL HEALTH 414, LLC; CARDINAL HEALTH PHARMACY SERVICES, LLC; WALMART INC. f/k/a WAL-MART STORES, INC.; and PHARMACY BUYING ASSOCIATION, INC., (the “Distributor Defendants”) shipped prescription opioids throughout the country, including Missouri and Ray County specifically. Rather than meet their obligations under Missouri law to report suspicious orders of controlled substances, the Distributor Defendants willfully ignored impossibly large orders being shipped to locations where it was inconceivable that any legitimate medical need could have required the quantities shipped. They failed to report these suspicious shipments despite their clear statutory and common law obligations to do so, and in contravention of their own internal policies and procedures. The Distributor Defendants’ breaches of their respective reporting obligations were willful, motivated by their desire to maximize profits, and were committed without consideration of the cost to Ray County or its citizenry.

### **C. The Devastating Effects of Defendants’ Conduct**

7. Each of the Defendants was fully aware that its products placed patients at an unreasonable risk of opioid-related addiction and/or death. Despite this knowledge, the Manufacturer Defendants continue to misrepresent the risks associated with prescription opioids and their efforts to influence physicians with the goal of increasing sales of prescription opioids to Ray County residents. Likewise, the Distributor Defendants continue to breach their duties under Missouri law to monitor, report, and prevent suspicious shipments of prescription opioids. This conduct precipitated the opioid crisis that has ravaged Plaintiff’s communities since the early 2000s, and will continue to do so for many years, even decades, to come. Defendants’ scheme has succeeded—Defendants have made untold billions of dollars from prescription opioids. Meanwhile, the death toll they have caused in Ray County and elsewhere is unconscionable.

8. Ray County dedicates substantial portions of its tax revenues to provide and pay for a broad array of services for its population, including, but not limited to, health

care, law enforcement and emergency medical services, and fire-rescue. However, as a result of the opioid epidemic, Ray County has been significantly hampered in its ability to continue to provide the requisite level of service in each of these categories for its residents. This creates a perverse dichotomy. The overburdened service areas require a *greater share* of Ray County's scarce tax dollars, while at the same time, the crisis itself *decreases* the tax dollars Ray County can generate. That is because opioid addiction takes productive members of society out of the economy, usually due to death or the inability to work. Simply put, most who become addicted to opioids are no longer able to work, and therefore are no longer able to care for their families, earn a paycheck or spend money in the same way they did before they fell victim to addiction. This predictable downward spiral means Ray County's tax revenues have suffered. These harms are the direct and proximate result of Defendants' scheme to increase their profits without regard for the end users of Defendants' drugs, or the municipalities that must bear the brunt of the increased demand for their services brought on by the epidemic.

9. Things were not always this way in Ray County. Though Defendants have been manufacturing, marketing, distributing, and/or selling prescription opioids for decades—including brand-name drugs like OxyContin and Percocet, as well as generic formulations such as oxycodone and hydrocodone—only since the late 1990s have Defendants' powerful narcotic painkillers been used to treat more than just short-term, acute or cancer-related pain. Indeed, for the vast majority of the twentieth century, Defendants' drugs were considered too addictive and debilitating for patients suffering from long-term (chronic) pain due to non-cancer conditions like arthritis, fibromyalgia and migraines.<sup>3</sup>

10. In the late 1990s, however, and continuing today, Defendants began a

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<sup>3</sup> In this Petition, “chronic pain” refers to non-cancer pain lasting three months or longer.

sophisticated marketing and distribution scheme premised on deception to persuade patients that opioids can and should be used to treat chronic pain. Defendants spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;<sup>4</sup> (2) promoted the concept of “pseudoaddiction,” falsely claiming that signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse by—*inter alia*—falsely claiming these opioids “cannot be crushed.” Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no credible evidence to support those benefits—a fact that Defendants not only knew at all times relevant to this action, but effectively suppressed and concealed.

11. At all times relevant to this action, Defendants knew their longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Moreover, regulators and the medical community at large have come to recognize the serious risks posed by opioid pain medications. Indeed, according to recently established and widely accepted clinical guidelines regarding opioid therapy, “[t]he science of opioids for chronic pain is clear: For

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<sup>4</sup> Addiction is classified as a spectrum of “substance use disorders” that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Petition, “addiction” refers to the entire range of substance abuse disorders. (See, e.g., American Society of Addiction Medicine (“ASAM”), Public Policy Statements, *Terminology Related to the Spectrum of Unhealthy Substance Use*, p. 1-2 (July 2013), [https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2\\_2](https://www.asam.org/docs/default-source/public-policy-statements/1-terminology-spectrum-sud-7-13.pdf?sfvrsn=d93c69c2_2).

the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits.”<sup>5</sup>

12. Opioid manufacturers, including Defendant Endo Pharmaceuticals, Inc., have also entered into agreements with public entities that prohibit them from making many of the misrepresentations identified in this Petition in other jurisdictions. Yet even now, Defendants continue to misrepresent the risks and benefits of long-term opioid use in Missouri, including in Ray County, and continue to fail to correct their past misrepresentations.

13. Specifically, Defendants concealed what their own internal documents and communications show they already knew, and had known for decades: not only were Defendants’ opioids both medically unnecessary and, in fact, life-threatening for non-cancer patients with chronic pain, but further, none of Defendants’ representations about the manageability or prevention of opioid addiction was true. As set forth in detail below, for decades, the Manufacturer and Distributor Defendants have made and continue to make a series of inaccurate claims about the risks and benefits associated with their opioids, essentially bribing Key Opinion Leader (“KOL”) group to substantiate the veracity of Defendants’ false statements. In creating the illusion that prescription opioids were a low risk treatment option for chronic pain relative to non-opioid pharmacologic approaches, Defendants successfully targeted vulnerable patient populations like the elderly. Defendants further tainted the sources that many prescribing healthcare providers and patients in Ray County relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles. As a result, Defendants successfully transformed the way healthcare providers treat chronic pain in Ray County, opening the floodgates of opioid prescribing and use. This explosion in opioid prescriptions and use has padded Defendants’ profit margins at the expense of

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<sup>5</sup> Thomas R. Frieden et al., *Reducing the Risks of Relief—The Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

chronic pain patients.

14. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in Missouri and, in particular, Ray County. Missouri faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it is an offense against the public order and economy and violates the public's right to life, health, and the use of property, while, at the same time, annoys, injures, endangers, renders insecure, interferes with, or obstructs the rights or property of the whole community, or neighborhood, or of any considerable number of persons. Public rights include the public health, the public safety, the public peace, the public comfort, or the public convenience. The effects of Defendants' deceptive marketing scheme are catastrophic and are only getting worse. These effects are devastating in Missouri. In 2010, Missouri had the 7<sup>th</sup> highest prescription drug overdose mortality rate in the country. In 2016, nearly three Missourians died each day from an opioid overdose at a rate of 1 out of every 66 deaths, a significant increase from 1 out of every 89 deaths in 2015.<sup>6</sup> In 2017, there were approximately 951 opioid or heroin-related deaths in Missouri at a rate of 16.5 deaths per 100,000 people, higher than the national rate of 14.6 deaths per 100,000 people.<sup>7</sup> As regulators acknowledged in February 2016, "[t]hings are getting worse, not better, with the epidemic of opioid misuse, abuse and dependence."

15. There is little doubt that Defendants' deceptive marketing and distribution scheme has precipitated this public health crisis in Missouri, including in Ray County, by

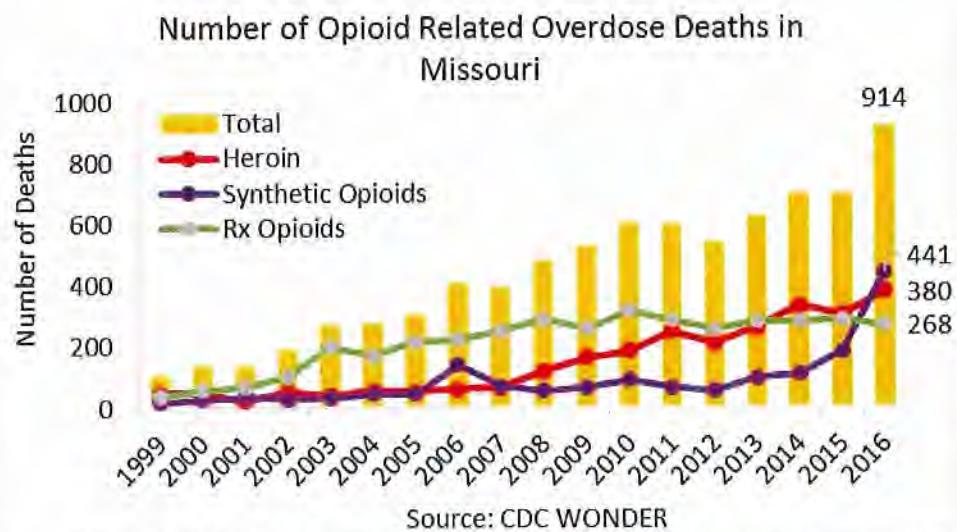
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<sup>6</sup> Missouri Hospital Association, *The Economic Cost of the Opioid Epidemic in Missouri* (January 2018), [https://www.mhanet.com/mhaindex/HIDIHealthStats/Feb2018HealthStats\\_Special\\_OpioidsEconomy.pdf](https://www.mhanet.com/mhaindex/HIDIHealthStats/Feb2018HealthStats_Special_OpioidsEconomy.pdf).

<sup>7</sup> National Institute on Drug Abuse, *Missouri Opioid Summary*, <https://www.drugabuse.gov/opioid-summaries-by-state/missouri-opioid-summary>.

dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

16. Defendants' deceptive marketing and distribution scheme have had further foreseeable impacts on Ray County. As a result of Defendants' conduct, Ray County must devote increased resources to mitigate the incidence of drug and property crimes, committed by individuals in order to feed their opioid-related addictions. For example, tax dollars are being used to maintain public safety of places where these individuals attempt to congregate, including parks, schools and public lands. Tax dollars are also required to fight the infectious disease brought by addicts, including Hepatitis B and C, HIV, sexually transmitted disease, methicillin-resistant *Staphylococcus aureus* ("MRSA"), and other diseases that have been demonstrated to be spread by opioid abuse.



17. Defendants' willful and wrongful conduct has further impacted Plaintiff by creating a public nuisance in Ray County, which Defendants foresaw, yet deliberately ignored. Defendants were aware at all relevant times when they deceptively marketed their

products as non-addictive that such addiction would be highly difficult to overcome.

18. The role of Defendants' deceptive marketing and distribution scheme in causing this public health crisis has become well recognized in recent years. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of regulators, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."<sup>8</sup> In the years since her comments were initially published, Dr. Volkow's message has become the dominant view of the top experts and influencers in the medical community, who are finally realizing just how addictive Defendants' opioids are, and how devastating the economic and social costs of Defendants' intentional deception has been.<sup>9</sup>

19. Absent the Manufacturer Defendants' deceptive marketing scheme and the Distributor Defendants' improper distribution, the opioid use, misuse, abuse, and addiction in Ray County would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

20. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims, despite their knowledge of the falsity of those claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising and unfair competition, but they have also created or assisted in the creation of a public nuisance.

21. Accordingly, Defendants' conduct, both individually and collectively, has violated and continues to violate Missouri's public nuisance laws. Ray County does not

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<sup>8</sup> N. Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse, (May 14, 2014), available at: <https://archives.drugabuse.gov/testimonies/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

<sup>9</sup> E. O'Brien, *Here's What it Would Cost to Fix the Opioid Crisis, According to 5 Experts*, Time Money (Nov. 27, 2017), <http://time.com/money/5032445/cost-fix-opioid-crisis/>.

ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Ray County seeks an order requiring Defendants to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law that cause and continue to cause harm to Ray County and its citizens, Ray County seeks a judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law, in an amount to be determined at trial.

22. By this action, Ray County further seeks to recoup tax dollars spent for the consequences of Defendants' wrongful conduct in causing the opioid epidemic and its impact on Ray County, and to abate the opioid nuisance so Ray County will not be required to spend further taxpayer dollars on the epidemic wrought by Defendants.

## **II. PARTIES**

### **A. Plaintiff**

23. Ray County, Missouri, by and through its attorneys hereto, brings this action so as to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance. Pursuant to Missouri law, Ray County, Missouri is a citizen of Missouri.

24. Ray County, Missouri, is located in northwest Missouri, just northeast of Kansas City. With Richmond serving as its county seat, Ray County is comprised of the cities of Camden, Crystal Lakes, Excelsior Springs, Fleming, Hardin, Henrietta, Lawson, Orrick, and Wood Heights. With a strong agricultural heritage and rich history, Ray County is home to approximately 23,354 citizens, the majority of which are families and seniors.

### **B. Manufacturer Defendants**

#### **1. Actavis/Allergan**

25. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc

in March 2015, and the combined company changed its name to Allergan plc in June 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. Defendant Actavis, LLC is a limited liability company formed in Delaware, headquartered in New Jersey, and, on information and belief, has members who are citizens of New Jersey and Pennsylvania. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is registered to do business in Missouri as a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Defendant Actavis plc is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States, including in Missouri and Ray County specifically. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to in this Petition as “Actavis.”)

26. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S. and Missouri and Ray County specifically. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

## **2. Cephalon**

27. Defendant Cephalon, Inc. (“Cephalon”) is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical

Industries, Ltd. (“Teva Ltd.”) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. It is registered to do business in Missouri.

28. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States, including in Missouri and Ray County specifically. Actiq has been approved by regulators only for the “management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain.” Fentora has been approved by regulators only for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

### 3. Teva

29. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States, including in Missouri and Ray County specifically. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The prescribing information and medication guide approved by regulators, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

30. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora.

Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva has engaged in consensual commercial dealings with Ray County's residents and has purposefully availed itself of the advantages of conducting business with and within Ray County. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon" for the remainder of this Petition.)

31. Notably, on May 26, 2019, Cephalon agreed to settle its lawsuit brought by the Oklahoma Attorney General on behalf of the State of Oklahoma for \$85 million dollars which accuses Cephalon (and other manufacturers) of creating a public nuisance through its production and marketing of prescription opioids.<sup>10</sup> Ray County alleges similar claims against Cephalon and its subsidiaries in this Petition.

#### 4. Endo

32. Defendant Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo").

33. Endo develops, markets, and sells prescription drugs, including the opioids

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<sup>10</sup> Oklahoma Attorney General, Press Release—*Attorney General Hunter Announces Settlement with Teva Pharmaceuticals*, (May 26, 2019), <http://www.oag.ok.gov/attorney-general-hunter-announces-settlement-with-teva-pharmaceuticals>.

Opana/Opana ER, Percodan, Percocet, and Zydome, in the U.S. and Missouri. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Missouri, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

### **5. Par**

34. Defendants Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") are New York corporations with their principal places of business in New York. Par was acquired by Endo in 2015. Par is the fifth largest manufacturer of generic pharmaceuticals in the world, including oxycodone, oxymorphone, and hydrocodone. At all times relevant, Par manufactured and marketed prescription opioids throughout the United States, including in Missouri and Ray County specifically. Par has engaged in consensual commercial dealings with Ray County's residents and has purposefully availed itself of the advantages of conducting business with and within Ray County. On information and belief, in 2013, Par pleaded guilty to misbranding its drugs.

### **6. Janssen**

35. Defendant Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc.) is registered to do business in Missouri as a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. These entities, which are collectively referred to herein as "Janssen," acted in concert with one another—as agents and/or principals of one another—in connection with the conduct described herein. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with regulators regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen

Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. The Janssen and J&J parties are collectively referred to as "Janssen."

36. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Missouri, and Ray County specifically, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER, which also generated substantial sales revenue for the company, accounting for \$172 million in sales in 2014 alone.

#### 7. Johnson & Johnson

37. Defendant Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey, imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code of conduct. Thus, the code of conduct governs all forms of marketing at issue in this case.

38. In addition, J&J made payments to front groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.<sup>11</sup>

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<sup>11</sup> U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, *Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, n. 23 ("Payments from Janssen include payments from Johnson & Johnson Health Care Systems, Inc.").

## 8. Mallinckrodt/SpecGX

39. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867, Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International Ltd. and renamed itself Covidien.

40. Defendant Mallinckrodt LLC is a limited liability company formed in Delaware and headquartered with its principal place of business in St. Louis, Missouri. Mallinckrodt LLC is a wholly owned subsidiary of Mallinckrodt, plc. According to a filing with the Secretary of State, Cathi M. Ponciroli is the designated manager of Mallinckrodt LLC, with a business address in Hazelwood, Missouri. Therefore, Mallinckrodt LLC is a citizen of the State of Missouri for jurisdictional purposes.

41. Defendant SpecGX LLC (“SpecGX”) is a limited liability company formed in Delaware and headquartered with its principal place of business in St. Louis, Missouri. SpecGX is a wholly owned subsidiary of Mallinckrodt plc. SpecGX’s regulatory filings indicate that Marvin Haselhorst is the designated member or manager of SpecGX with a business address in Webster Groves, Missouri. According to its Drug Enforcement Agency application, SpecGX registered its manufacture its products at the address of 3600 North Second Street, St. Louis, Missouri 63147. Consequently, SpecGX is a citizen of the State of Missouri for jurisdiction purposes and this matter is properly venued in St. Louis City.

42. Together, Mallinckrodt plc, Mallinckrodt LLC, and SpecGX LLC (collectively, “Mallinckrodt”) manufacture, market, and sell drugs in the United States, including in Missouri and Ray County specifically. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of

oxycodone in the U.S.

43. Mallinckrodt currently manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In addition, Mallinckrodt previously developed, promoted, and sold the following branded opioid products: Magnacet, TussiCaps, and Xartemis XR.

44. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that, in 2015, its controlled substances made up approximately 25% of one regulator's entire annual quota for controlled substances. Mallinckrodt also estimated, based on health data for the same period, that its generics claimed an approximately 23% market share of controlled opioids and oral solid dose medications.

45. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups throughout the United States, including in Missouri and Ray County specifically.

## 9. Sandoz

46. A subsidiary of Novartis International AG, Defendant Novartis Pharmaceuticals Corporation f/k/a Sandoz, Inc. ("Sandoz") is headquartered in Princeton, New Jersey and develops, manufactures, markets and distributes generic pharmaceutical products, including fentanyl. At all times relevant, Sandoz manufactured and marketed prescription opioids throughout the United States, including in Missouri and Ray County specifically. On information and belief, Sandoz is a top manufacturer of fentanyl to Ray County.

## **10. Mylan**

47. Defendant Mylan Institutional Inc. (“Mylan Institutional”) is an Illinois corporation headquartered in Rockford, Illinois. Mylan Institutional manufactures and markets pharmaceutical products. Defendant Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”) is based in Morgantown, West Virginia, and is also a major manufacturer and marketer of opioids in Ray County. Both Mylan Institutional and Mylan Pharmaceuticals are subsidiaries of Defendant Mylan Pharmaceuticals NV (“Mylan NV”), which is the second-largest generic and specialty pharmaceuticals company in the world, registered in the Netherlands with principal executive offices in Hatfield, Hertfordshire, UK and a global center in Canonsburg, Pennsylvania. Together, at all times relevant to this action, Mylan Institutional, Mylan Pharmaceuticals, and Mylan NV (collectively, “Mylan”) manufactured and marketed prescription opioids throughout the United States, including in Missouri and Ray County specifically. On information and belief, Mylan is a top manufacturer of fentanyl, oxycodone, morphine, and codeine in Ray County.

## **11. Hospira**

48. Defendant Hospira, Inc. (“Hospira”), a Delaware corporation, with its principle place of business in Lake Forest, Illinois and is the former hospital-products division of Abbott Laboratories. Hospira was the world’s largest producer of generic injectable pharmaceuticals before being acquired by Pfizer in September 2015.

49. At all times relevant to this action, Hospira manufactured and marketed opioids across the county and in Missouri and Ray County specifically. On information and belief, Hospira is a top manufacturer of fentanyl, morphine, hydromorphone, meperidine and buprenorphine in Ray County.

## **12. West-Ward**

50. Defendant Hikma Pharmaceuticals USA Inc. f/k/a West-Ward Pharmaceuticals Corp. is headquartered in Eatontown, New Jersey and manufactures, markets and/or distributes opioids such as fentanyl and morphine. West-Ward

Pharmaceuticals Corp. (“West-Ward”) is a wholly owned subsidiary of Hikma Pharmaceuticals plc, and represented 51% of Hikma’s group sales in 2014. Since acquiring Baxter Healthcare Corporation’s Multi-Source Injectables division in 2011, West-Ward has become the second largest injectable supplier by volume in the country. At all times relevant, West-Ward manufactured and marketed prescription opioids throughout the United States, including in Missouri and Ray County specifically.

**13. The Insys Individual Defendants: John Kapoor and Michael Babich**

51. Insys Therapeutics, Inc. (“Insys”) is a Delaware corporation with its principal place of business in Chandler, Arizona and is registered to do business in Missouri. Insys manufactures, markets, sells and distributes nationwide several types of opioids, including Subsys—a fentanyl sublingual spray and semi-synthetic opioid antagonist—as well as Syndros, a cannabinoid medicine used in adults to treat common side-effects of opioid use, particularly for patients whose nausea and vomiting have not improved with usual anti-nausea and vomiting medicines. Subsys and Syndros were approved for widespread use in 2012 and 2016, respectively.

52. Subsys is indicated “for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain.”<sup>12</sup> The indication also specifies that “Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.” In addition, the indication provides that “[p]atients must remain on

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<sup>12</sup> The indication provides that “[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer.”

around-the-clock opioids when taking SUBSYS.” Subsys is contraindicated for, among other ailments, the “[m]anagement of acute or postoperative pain including headache/migraine and dental pain.” It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

53. Insys’ revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of \$331 million. Of that total, \$329.5 million was derived from sales of Subsys. The majority of Insys’ sales of Subsys are through wholesalers, including Defendants AmerisourceBergen and Cardinal Health. In 2015, those wholesalers respectively comprised 20% and 14% of Insys’ total gross sales of Subsys.

54. On June 7, 2019, the pharmaceutical arm of Insys formally pleaded guilty charges connected to allegations that the company bribed healthcare providers to prescribe a powerful opioid to patients who did not need it, as part of Insys’ \$225 million dollar settlement to resolve these allegations in Massachusetts.

55. Defendant John Kapoor is the founder and majority owner of Insys. In October of 2017, Kapoor was arrested and charged with various violations of fraud and abuse laws as well as conspiracy, for his alleged participation in a nationwide scheme to bribe healthcare providers in various states, including Missouri, to prescribe Subsys. On May 2, 2019, he was found guilty of these charges in connection with running a nationwide bribery scheme.<sup>13</sup> He is a citizen of Phoenix, Arizona, and a current member of the Board of Directors of Insys.

56. Defendant Michael Babich is the former CEO and President of Insys. In 2017, he was also arrested on charges of various violations of fraud and abuse laws as well as conspiracy, in connection running a nationwide bribery scheme intended to bribe or

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<sup>13</sup> Gabrielle Emanuel, *Opioid Executive John Kapoor Found Guilty in Landmark Bribery Case* (May 2, 2019) <https://www.npr.org/2019/05/02/711346081/opioid-executive-john-kapoor-found-guilty-in-landmark-bribery-case>

deceive healthcare providers in various states, including Arizona, to prescribe Subsys. In January of 2019, Defendant Babich pleaded to these charges.<sup>14</sup> In January 2019, Babich pleaded to these charges.<sup>15</sup> He is a citizen of Scottsdale, Arizona.

### **C. Distributor Defendants**

#### **1. AmerisourceBergen**

57. Defendant Distributor AmerisourceBergen Drug Corporation is a publicly traded company headquartered in Pennsylvania and incorporated under the laws of Delaware. It is registered to do business in Missouri. Defendant Distributor AmerisourceBergen Corporation is the parent company of AmerisourceBergen Drug Corporation. (AmerisourceBergen Drug Corporation and AmerisourceBergen Corporation are collectively referred to herein as “AmerisourceBergen.”) AmerisourceBergen is in the chain of distribution of prescription opioids. At all relevant times, AmerisourceBergen was in the business of distributing substantial amounts of prescription opioids to providers and retailers. AmerisourceBergen has engaged in consensual commercial dealings in Ray County, and has purposefully availed itself of the advantages of conducting business with and within Ray County.

#### **2. Cardinal Health**

58. Defendant Distributor Cardinal Health Inc. is an Ohio pharmacy wholesaler and drug distribution corporation with its headquarters in Dublin, Ohio. Defendant Distributor Cardinal Health 100, Inc. is an Indiana corporation with its principal place of

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<sup>14</sup> Jonathan Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, Boston Globe (Feb. 12, 2019), <https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-opioid/aZhLcDENayOO3dzPlFn9gN/story.html>

<sup>15</sup> Jonathan Saltzman, *Former CEO says Insys founder pushed for higher doses of opioid*, Boston Globe (Feb. 12, 2019), <https://www2.bostonglobe.com/business/2019/02/12/former-ceo-says-insys-founder-pushed-for-higher-doses-opioid/aZhLcDENayOO3dzPlFn9gN/story.html>.

business located in Dublin, Ohio. Defendant Distributor Cardinal Health 108, LLC is a limited liability company formed in Delaware with its principal place of business located in LaVergne, Tennessee. On information and belief, at least one of Cardinal Health 108, LLC's members is a citizen of Ohio. Defendant Distributors Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 414, LLC; and Cardinal Health 5, LLC are limited liability companies formed in Delaware with their principal place of business in Dublin, Ohio. Upon information and belief, at least one of Cardinal Health 110, LLC's; Cardinal Health 200, LLC's; Cardinal Health 414, LLC's; and Cardinal Health 5, LLC's members is a citizen of Ohio. Defendant Cardinal Health 201, Inc. is a for-profit Delaware corporation with its principal place of business in Dublin, Ohio. Defendant Distributor Cardinal Health 122, LLC is a limited liability company formed in Delaware with its principal place of business in Ellicott City, Maryland. Upon information and belief, at least one of Cardinal Health 122, LLC's members is a citizen of Ohio. Defendant Distributors Cardinal Health 132, LLC and Cardinal Health Pharmacy Services, LLC are limited liability companies formed in Delaware with their principal place of business in Houston, Texas. Upon information and belief, at least one of Cardinal Health 132, LLC's and Cardinal Health Pharmacy Services, LLC's members is a citizen of Ohio. Defendant Distributor Cardinal Health 113, LLC is a limited liability company formed in Wisconsin with its principal place of business in Germantown, Wisconsin. Upon information and belief, at least one of Cardinal Health 113, LLC's members is a citizen of Ohio. (Cardinal Health, Inc.; Cardinal Health 100, Inc.; Cardinal Health 108, LLC; Cardinal Health 110, LLC; Cardinal Health 200, LLC; Cardinal Health 201, Inc.; Cardinal Health 414, LLC; Cardinal Health 5, LLC; Cardinal Health 122, LLC; Cardinal Health 132, LLC; Cardinal Health Pharmacy Services, LLC; and Cardinal Health 113, LLC are all registered to do business in Missouri and shall collectively be referred to as "Cardinal Health.") At all relevant times, Cardinal Health was in the business of distributing substantial amounts of prescription opioids to providers and retailers. Cardinal Health has engaged in consensual

commercial dealings in Ray County, and has purposefully availed itself of the advantages of conducting business with and within Ray County. Cardinal Health is in the chain of distribution of prescription opioids.

### **3. Walmart**

59. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. (“Walmart”) is a Delaware corporation with its principal place of business in Arkansas.

60. At all times relevant, Walmart distributed prescription opioids throughout the United States, including in Missouri and Ray County specifically. On information and belief, these opioids were distributed to Ray County by at least two Walmart entities—i.e., Wal-Mart Pharmacy Warehouse #1 (located at 2252 North 8<sup>th</sup> Street in Rogers, AR) and Wal-Mart Pharmacy WHSE #45 (located at 2250 North 8<sup>th</sup> Street, Suite 102-A in Rogers, AR)—to just one buyer in Ray County: Wal-Mart Pharmacy 10-0325, based in Richmond, Missouri. On information and belief, Walmart is a top distributor of fentanyl, oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, methadone, and buprenorphine in Ray County. Walmart has engaged in consensual commercial dealings in Ray County and has purposefully availed itself of the advantages of conducting business with and within Ray County. Walmart is in the chain of distribution of prescription opioids.

### **4. Pharmacy Buying Association, Inc.**

61. Defendant Pharmacy Buying Association, Inc. (“PBA”) is a Missouri corporation with its principal place of business in Kansas City, Missouri. PBA provides services to community pharmacies, independent retail pharmacy chains, hospitals, and clinics, including purchasing, inventory management, branding, and cost-efficiency services.

62. At all times relevant, PBA distributed prescription opioids throughout the United States, including in Missouri and Ray County specifically. On information and belief, PBA’s share of the opioid market in Ray County is substantial, both in terms of the number of opioid pills distributed by PBA as well as PBA’s proportional share of the

overall MME market in Ray County. PBA is a top distributor of fentanyl, oxycodone, oxymorphone, hydrocodone, morphine, methadone, codeine, tapentadol, dihydrocodeine, and meperidine in Ray County.

63. Defendants AmerisourceBergen, Cardinal Health, Walmart, and PBA are collectively referred to as the “Distributor Defendants.” Manufacturers of opioids have transferred prescription opioids to the Distributor Defendants for years. The Distributor Defendants dominate 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at \$378.4 billion in 2015. The Distributor Defendants supplied opioids to hospitals, pharmacies (including their own retail stores), doctors and other healthcare providers, which then dispensed the drugs to patients in Missouri, including in Ray County. The Distributor Defendants have had substantial contacts and business relationships with the citizens of Ray County. The Distributor Defendants have purposefully availed themselves of business opportunities within Ray County.

#### **D. DOE Defendants**

64. The true names and capacities, whether individual, plural, corporate, partnership, associate, or otherwise, of DOES 1 through 1000, inclusive, are unknown to Ray County who therefore sues said Defendants by such fictitious names. The full extent of the facts linking such fictitiously sued Defendants is unknown to Ray County. Ray County is informed and believes and thereon alleges that each of the Defendants designated herein as a DOE was, and is, negligently, recklessly, and/or intentionally responsible for the events and happenings hereinafter referred to, and thereby negligently, recklessly, and/or intentionally legally and proximately caused the hereinafter described injuries and damages to Ray County. Ray County will hereafter seek leave of the Court to amend this Petition to show the fictitiously sued Defendants’ true names and capacities, after the same have been ascertained.

#### **III. JURISDICTION AND VENUE**

65. This Court has subject matter jurisdiction by grant of authority under the

Constitution of the State of Missouri.

66. This Court has personal jurisdiction over Defendants. Plaintiff is a “resident” of the State of Missouri. Defendants regularly transact business in the State of Missouri and engage in tortious activities, including false and misleading advertising and unlawful, unfair, and deceptive business practices, and create or assist in the creation of a public nuisance in Missouri, including in Ray County. Further, Defendants, individually, through their agents, and through their co-conspirators, have placed into the stream of commerce highly addictive prescription opioids, with the knowledge that those products would be marketed, distributed and sold in the State of Missouri. Because Defendants have regularly transacted business activities in Missouri; have purposefully directed business activities to Missouri; and have engaged in unlawful practices and caused injury in Missouri, this Court also has personal jurisdiction over Defendants under the United States Constitution. Each Defendant has promoted, marketed, sold and/or distributed prescription opioids in the State of Missouri or directed such promotion, marketing, selling and/or distribution to the State of Missouri.

67. Venue is proper in the Circuit Court of St. Louis City. Defendant SpecGX registers its address within this venue, located at 3600 North Second Street, St. Louis, Missouri 63147. Pursuant to Mo. Rev. Stat. § 508.010.6, Plaintiff may properly commence and prosecute to final judgment, within the county in which a defendant resides. Further, SpecGX conducts business and continues to conduct business in Ray County.

68. Plaintiff’s causes of action assert no federal question or statute, and therefore do not arise under federal law. Plaintiff asserts only state law causes of action. Plaintiff specifically denies any intent to state a cause of action arising under the laws of the United States of America, including any claim for injunctive relief available under federal law.

#### **IV. FACTUAL ALLEGATIONS**

##### **A. Background on Pain Medicine**

69. The practice of medicine centers on informed risk management. Prescribers

must weigh the potential risks and benefits of each treatment option, as well as risk of non-treatment. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risk of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

70. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction, and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, some types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

71. During the Civil War, opioids gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain—particularly on the battlefield—and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States. Both the number of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

72. Due to concerns about their addictive properties, opioids have been regulated for decades. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

73. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed poor outcomes from long-term opioid therapy in pain management programs; opioids’ mixed record in reducing pain long-term and failure to improve patients’ function; greater pain complaints as most patients developed tolerance to opioids; opioid patients’ diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid

therapy for chronic pain.

74. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use. On the contrary, evidence shows that opioid drugs are not effective to treat chronic pain and may worsen patients' health. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

75. Opioids are highly addictive. Patients using opioids for more than a few days can experience severe withdrawal symptoms if they stop taking the drugs, including: anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors. Withdrawal can last so long and be so painful that it is difficult to stop taking opioids.

76. Putting patients on opioids puts them at risk. Patients who take opioids at higher doses and for longer periods face higher and higher risk of addiction and death. Relative to the general population, the risk of opioid-death is 35-times higher for patients receiving three consecutive months of opioid therapy. Each of the Defendants named in this Petition disregarded the well-known and frightening statistics regarding opioid abuse and chose to ignore them in the name of profits.

#### **B. The Manufacturer Defendants' Impact on the Perception and Prescribing of Opioids**

77. Before the Manufacturer Defendants began the marketing campaign complained of herein, the generally accepted standards of medical practice dictated that opioids should only be used short-term, for acute pain, or for patients nearing the end of life. The Manufacturer Defendants changed this perception and took advantage of addiction to make money. The Manufacturer Defendants' marketing campaign resulted in skyrocketing opioid prescriptions. The shocking increase in prescriptions has been a gold mine for the Manufacturer Defendants. It has been a tragedy for patients and Ray County's

citizenry. Ray County has lost citizens young and old to the opioid epidemic—too many children in Ray County have lost their parents and too many parents have buried their children. Too many grandparents are raising their grandchildren.

78. Patients who survive addiction need lengthy, difficult, and expensive treatment. People who are addicted to opioids are often unable to work. The addiction of parents can force their children into foster care. Babies are born addicted to opioids, a condition known as Neonatal Abstinence Syndrome (“NAS”), because they are exposed to the drugs in the womb. Addiction in young adults in Missouri is also on the rise. In 2017, the peak age group for heroin- and non-heroin-involved overdose deaths was 25 to 34 compared to 2011-2015, where the peak age group for overdose deaths was 45 to 54.<sup>16</sup> Additionally, the Manufacturer Defendants’ misconduct has imposed heavy costs on Missourians and the citizens of Ray County at the tune of approximately \$12.6 billion dollars as of 2016.<sup>17</sup>

### **C. The Manufacturer Defendants Engaged in a Deceptive Marketing Scheme to Increase Profits**

79. To profit from their highly addictive drugs, the Manufacturer Defendants engaged in deadly and illegal practices to deceive prescribing healthcare providers and patients. First, the Manufacturer Defendants deceived Ray County healthcare providers and patients to get more people on their highly addictive drugs. Second, the Manufacturer Defendants misled them to take higher and more dangerous doses. Third, the Manufacturer Defendants deceived them to stay on their drugs for longer and more harmful periods of

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<sup>16</sup> Bureau of Vital Statistics, Missouri Department of Health and Senior Services, *2017 Missouri Resident Overdose Deaths*, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-10.pdf>.

<sup>17</sup> Missouri Hospital Association, *The Economic Cost of the Opioid Epidemic in Missouri* (January 2018), [https://www.mhanet.com/mhainages/HIDIHealthStats/Feb2018HealthStats\\_Special\\_OpioidsEconomy.pdf](https://www.mhanet.com/mhainages/HIDIHealthStats/Feb2018HealthStats_Special_OpioidsEconomy.pdf).

time.

80. The Manufacturer Defendants targeted vulnerable people who could be introduced to opioids, including elderly patients and people who had never taken opioids before. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. Existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. Clinical guidelines for opioid therapy therefore conclude that there are “special risks of long-term opioid use for elderly patients” and recommend that prescribers use “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients.

81. All the while, the Manufacturer Defendants peddled falsehoods to keep patients away from safer alternatives. Even when the Manufacturer Defendants knew people in Ray County were addicted and dying, the Manufacturer Defendants treated prescribing healthcare providers and patients as “targets” to sell more drugs.

82. Each part of the scheme earned the Manufacturer Defendants more money from opioid sales and caused more addiction and death in Ray County. And each Manufacturer Defendant participated in and profited from the scheme in Ray County, as set forth below.

#### **D. The Manufacturer Defendants Funneled Misrepresentations Through Sales Representatives, Advertisements, and Third Parties**

83. Patients across the county, including patients in Missouri and Ray County, continue to visit emergency rooms and/or die after taking the Manufacturer Defendants’ drugs because Ray County was subject to the Manufacturer Defendants’ massive deceptive sales campaign. The Manufacturer Defendants deceptively marketed their branded opioids directly to these healthcare providers and patients in Ray County alike. The Manufacturer Defendants also deployed sales representatives to spread their false and misleading statements about the risks and benefits of opioids for the long-term treatment of chronic

pain throughout Missouri and, specifically, in Ray County.

84. These representatives were the Manufacturer Defendants' most powerful tools of deception by using them to conduct face to face meetings with Ray County healthcare providers and pharmacists across the county in an effort to promote opioids. During sales visits, the Manufacturer Defendants' representatives made false and misleading claims directly to the professionals who care for Ray County patients. The Manufacturer Defendants assigned representatives to Ray County and gave them lists of Ray County healthcare providers to visit. The 'scripts' used by these representatives were approved and closely monitored by Manufacturer Defendants.

85. Each of these visits cost the Manufacturer Defendants money. But the Manufacturer Defendants made this money back many times over, because they convinced healthcare providers to prescribe their addictive drugs. The Manufacturer Defendants rewarded high prescribing healthcare providers with meals, money, and gifts. The Manufacturer Defendants' sales representatives who generated the most prescriptions won bonuses and prizes. These representatives have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, and other healthcare providers, including those in Ray County.

86. The Manufacturer Defendants' representatives have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by regulators required Actavis to acknowledge to the healthcare providers to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

87. The Manufacturer Defendants also conducted and continue to conduct advertising campaigns touting the purported benefits of their branded drugs. For example,

the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included \$8.3 million by Purdue (which is not a defendant herein, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants), \$4.9 million by Janssen, and \$1.1 million by Endo.

88. A number of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction workers and chefs, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue (which is not a defendant herein, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants) also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they continue to disseminate them in Missouri.

89. Similarly, despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors and other healthcare providers as an effective treatment for back pain, neck pain and other off-label breakthrough pain conditions. As of June 2012, Insys defined "breakthrough pain" in cancer patients to include mild pain: a "flare of mild-to-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Dr. Russell Portenoy.<sup>18</sup> Insys trained and instructed its sales representatives to use the false

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<sup>18</sup> Portenoy's paper, which was featured in the 1990 issue of Pain, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity—i.e.,

definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

90. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others, including dentists and podiatrists, writing prescriptions as well.<sup>19</sup>

91. On September 6, 2017, Senator Claire McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the System Manipulation of Prior Authorization" was published. The report found that Insys manipulated the prior authorization process<sup>20</sup> by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.<sup>21</sup>

92. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

"The opioid epidemic is the direct result of a calculated marketing and sales

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to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

<sup>19</sup> Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. TIMES (May 13, 2014), [https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsy...a-strong-painkiller.html](https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsy...).

<sup>20</sup> Prior authorization (PA) is any process by which physicians and other health care providers must obtain advance approval from a health plan before a specific procedure, service, device, supply or medication is delivered to the patient to qualify for payment coverage. (American Medical Association, *Prior authorization: The current landscape*, p. 1 (2015), [https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-toolkit\\_0.pdf](https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/psa/prior-authorization-toolkit_0.pdf).

<sup>21</sup> HSGAC Minority Staff Report, *Insys Therapeutics and the Systemic Manipulation of Prior Authorization* (2017).

strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out these messages were exaggerations at best and outright lies at worst.

\* \* \*

Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.<sup>22</sup>

93. Less than two years later, Insys' former chief executive officer pleaded guilty to participating in a nationwide scheme to bribe healthcare providers in exchange for prescribing Subsys.<sup>23</sup>

94. The Manufacturer Defendants<sup>24</sup> also identified healthcare providers to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs provided: (1) an incentive for healthcare providers to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the healthcare providers selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

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<sup>22</sup> See, *LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, September 12, 2017, at 31:03-31:37, [https://www.youtube.com/watch?v=k9mrQa8\\_vAo](https://www.youtube.com/watch?v=k9mrQa8_vAo) (last accessed Mar. 17, 2019).

<sup>23</sup> Nate Raymon, Former Insys CEO pleads guilty to opioid kickback scheme, REUTERS (Jan. 9, 2019), <https://www.reuters.com/article/us-insys-opioids/former-insys-ceo-pleads-guilty-to-opioid-kickback-scheme-idUSKCN1P312L>.

<sup>24</sup> Upon information and belief, Actavis continued to carry out speaker programs after it acquired Kadian.

95. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts (“detailing”) with doctors and other prescribers. In 2014 alone, the Manufacturer Defendants spent \$168 million on detailing branded opioids to prescribers. This amount is twice as much as the Manufacturer Defendants spent on detailing in 2000. The amount includes \$34 million by Janssen, \$10 million by Endo, and \$2 million by Actavis.

96. The Manufacturer Defendants also deceptively marketed opioids in Missouri through unbranded advertising—*i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.<sup>25</sup>

97. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by regulators. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive healthcare providers and patients about the risks and benefits of long-term opioid use for chronic pain.

98. The Manufacturer Defendants’ deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by regulators. For example, Endo’s unbranded advertising contradicted its concurrent, branded advertising

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<sup>25</sup> The phrase “acted in concert” includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
<p>“People who take opioids <b>as prescribed</b> usually do not become addicted.”</p>	<p>“All patients treated with opioids require careful monitoring for signs of abuse and addiction, since <b>use of opioid analgesic products carries the risk of addiction even under appropriate medical use.</b>”</p>

99. The Manufacturer Defendants also spoke through a small circle of healthcare providers who, upon information and belief, were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These providers became known as “key opinion leaders” or “KOLs.” The Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs (“CMEs”), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing their marketing goals. KOLs’ professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the Manufacturer Defendants.

100. Pro-opioid healthcare providers are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use for chronic pain. The Manufacturer Defendants know that doctors and other prescribers rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the New York Attorney General (“NY AG”) found

in its settlement with Purdue, which is owned and controlled by the Sackler family, (neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants) that through March 2015, the Purdue website, “In the Face of Pain,” failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles, and have given speeches and CMEs supportive of chronic opioid therapy. The Manufacturer Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

101. The Manufacturer Defendants’ KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they were created, and they are not supported by the scientific evidence today. The Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. The medical community at large as well as several regulatory agencies and government entities confirm and recognize that treatment guidelines can “change prescribing practices.”

102. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these “Front Groups”—which include, but are not limited to, the American Pain Foundation (“APF”) and the American Academy of Pain Medicine—generated treatment guidelines, unbranded

materials, and programs that favored chronic opioid therapy. These guidelines, materials, and programs were not supported by the evidence at the time they were created, and they are not supported by the scientific evidence today. These Front Groups also assisted the Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

103. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients were suffering from pain or doctors were treating those patients.

104. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, the Manufacturer Defendants combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Endo, Janssen/J&J, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that legally mandated education project on opioids were not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing. PCF also worked to address a perceived “lack of coordination” among its members and developed “key” messages that were disseminated in programs and industry-run websites.

**E. The Manufacturer Defendants Deceived Healthcare Providers and Patients to Get More People on Highly Addictive Drugs, at Higher Doses, for Longer Periods**

105. To convince prescribers and patients around the country, including in Missouri, that opioids can and should be used to treat chronic pain, the Manufacturer Defendants had to convince them that long-term opioid use is both safe and beneficial. The Manufacturer Defendants deceived those doctors and patients about the risks and benefits of long-term opioid use. The Manufacturer Defendants, through Front Groups, KOLS, and advertisements, made claims that were not supported by or were contrary to the scientific evidence—most frequently, these claims downplayed the risks of addiction in order to convince patients and doctors alike that prescription opioids should be used more regularly. Even though pronouncements by and guidance from regulators based on that evidence confirm that their claims were false and misleading, Ray County is informed and believes that the Manufacturer Defendants have not corrected them and continue to spread them today, including as set forth specifically below.

**1. Deception about Addiction**

106. The Manufacturer Defendants always knew that their opioids carry grave risks of addiction and death. Instead of being honest about these risks, the Manufacturer Defendants obscured them, including by falsely stating and implying that “appropriate patients” won’t get addicted. To convince doctors and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by regulators and the medical community at large.

107. First, the Manufacturer Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made

by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011, are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Purdue, which is owned and controlled by the Sacklers (neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants), and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."
- d. Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website [www.opana.com](http://www.opana.com).
- e. Janssen/J&J reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen ran a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue, which is owned and controlled by the Sacklers (neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named

manufacturer defendants), sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*—which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[].”

- h. Detailers for Purdue, Endo, Teva and Janssen in Missouri have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in Missouri, including Ray County, about the risk of addiction; falsely claiming that abuse-deterrant formulations “cannot be crushed,” downplaying the potential that these opioids could be abused; and routinely did not correct the misrepresentations noted above.

108. Moreover, Purdue, in a pamphlet for doctors, *Providing Relief, Preventing Abuse: A Reference Guide to Controlled Substance Prescribing Practices*, wrote that addiction “is not caused by drugs.” Instead, Purdue—which is owned and controlled by the Sacklers (neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants)—assured doctors that addiction happens when the wrong patients get drugs and abuse them: “it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse.”<sup>26</sup>

109. Purdue, which is owned and controlled by the Sacklers (neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants), also promoted its opioids to Ray County patients with marketing that was designed to obscure the risk of addiction and even the fact that Purdue was behind the campaign. Purdue created a website, *In the Face of Pain*, that promoted pain treatment by urging patients to

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<sup>26</sup> Purdue Pharma LP, *Providing Relief, Preventing Abuse* (2008), pg. 12; see also K. Nelson, *Purdue Pharma lawsuit: Terms you need to know to understand OxyContin blitz*, Knox News (July 13, 2018), <https://www.knoxnews.com/story/news/health/2018/07/13/purdue-pharma-lawsuit-terms-know-understand-oxycontin-blitz/779173002/>.

“overcome” their “concerns about addiction.” Testimonials on the website that were presented as personal stories were in fact by Purdue consultants, whom Purdue had paid tens of thousands of dollars to promote its drugs.<sup>27</sup>

110. Another publication from Purdue—which is owned and controlled by the Sacklers—was the *Resource Guide for People with Pain*, which falsely assured patients and doctors that opioid medications are not addictive:

*“Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief—not a ‘high’.”<sup>28</sup>*

111. Purdue, which is owned and controlled by the Sacklers, falsely denied the risk of addiction, falsely implied that addiction requires patients to get “high,” and falsely promised that patients would not get addicted if they took opioids as prescribed.

112. Purdue (which is not a defendant in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants) funded and distributed many more publications that were similarly misleading. *Exit Wounds* misleadingly claimed: “Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications.”<sup>29</sup>

113. Similarly, while Janssen/J&J repeatedly disclaimed responsibility for its part in causing the opioid crisis, insisting that “[e]verything that we have done with our products when we’ve promoted opioid products . . . was appropriate and responsible,” internal memoranda and communications between high-level executives at Janssen show the

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<sup>27</sup> Purdue Pharma LP, *In the Face of Pain* (Oct. 24, 2011).

<sup>28</sup> Purdue Pharma LP, *Resource Guide for People with Pain*, p. 8 (2009).

<sup>29</sup> Purdue Pharma LP, *Exit Wounds*, p. 107 (2009).

company funded and pushed bogus research to lend false credibility to a series of dangerous fictions, claiming that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain,” and enabling “Janssen’s representatives [to] promote[] Nucynta and Nucynta ER as safer, milder, and less addictive than competitor opioids like OxyContin.”<sup>30</sup>

114. In 2017, Mallinckrodt agreed to settle for \$35 million allegations regarding excessive sales of oxycodone in Florida. These allegations state that even though Mallinckrodt knew its oxycodone was being diverted for illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify regulators of the suspicious orders in violation of its legal obligations as an opioid distributor. Similarly, in 2008, Cephalon pled guilty to a criminal violation for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

115. In August 2019, Johnson & Johnson was found liable of: (a) having engaged in false and misleading marketing of both their drugs and opioids more generally; and (b) creating, contributing to, and perpetuating a public nuisance under Oklahoma law. This determination resulted in a \$572 million verdict that represents just one year of abatement expenses in one state.

116. Over and over, Defendants said opioids could be given to “trusted” patients without risk of addiction. To promote their drugs, the Manufacturer Defendants pushed the myth that addiction is a character flaw, and “trustworthy” people do not get addicted to drugs.

117. These claims are contrary to longstanding scientific evidence and recently established clinical guidelines for opioid therapy. These guidelines describe the “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative

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<sup>30</sup> M. Aron, *Deceptively marketing opioids*, NJTV News (Nov. 13, 2018), <https://www.njtvonline.org/news/video/state-sues-johnson-johnson-subsidiary-for-deceptively-marketing-opioids/>.

term for opioid addiction]).” The guidelines indicate “[o]pioid pain medication use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”

118. The falsity of the Manufacturer Defendants’ claims about the low risk of addiction was further exposed when regulators announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. These announcements emphasize that “most opioid drugs have ‘high potential for abuse’ ” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” Further, these announcements clarify the risk of death is not limited to patients who seek drugs illicitly, as addiction “can occur in patients appropriately prescribed [opioids].” Thus, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed.

119. The New York Attorney General, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.” Endo had claimed until at least April 2012 on its [www.opana.com](http://www.opana.com) website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. On information and belief, Endo made similar misrepresentations to healthcare providers and patients in and around Ray County, Missouri. However, Endo has not been restricted from making these statements in

Missouri.

## 2. Deception to Get Vulnerable Patients on Opioids

120. To expand the market for opioids, the Manufacturer Defendants also trained their representatives to target vulnerable populations and encourage doctors to put them on opioids, without disclosing the risks. The Manufacturer Defendants deceptively promoted opioids for elderly patients, patients who had never taken opioids, and patients with osteoarthritis—putting thousands of more patients at risk.

### Elderly Patients

121. The Manufacturer Defendants knew that prescribing opioids to elderly patients increase their risk of death. Elderly patients are at a greater risk of dangerous interactions between drugs. They are also at a greater risk of respiratory depression—in which patients suffocate and die. But the Manufacturer Defendants saw the opportunity to earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. For instance, Purdue’s (not a defendant herein) internal documents show it targeted “Patients over the age of 65 as more . . . coverage is achieved.”<sup>31</sup>

### Opioid-Naïve Patients

122. The Manufacturer Defendants also targeted patients who were not already taking opioids, described in the field as “opioid-naïve.” The Manufacturer Defendants unfairly and deceptively marketed their drugs as appropriate treatments for opioid-naïve patients, without disclosing that they face even higher risks of overdose and death.

**CLOSE #1**  
Opioid-naïve (5 mcg/hour):

- “Doctor, either today or tomorrow, do you anticipate seeing this commercially insured, opioid-naïve patient with moderate to severe chronic pain, who you believe would benefit from Butrans?”

*Purdue sales script from 2011*

123. For instance, Purdue trained its sales reps to promote their drugs specifically

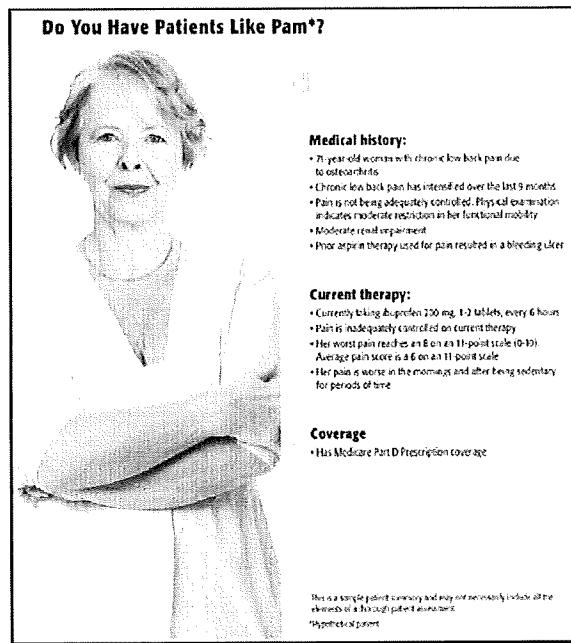
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<sup>31</sup> Purdue Pharma LP, *Pain Products Presentation*, p. 12 (Jan. 28, 2015).

for opioid-naïve patients. In training calls, Purdue managers instructed:

- *“Your opportunity here is with the naïve community, let’s use the naïve trial to make the case.”*
- *“You created an epiphany with the doctor today (potentially) by reviewing the opiate naïve patient profile. What made him more apt to write this for his patient, being an amiable doctor, is the fact that he would not have to talk patients out of their short-acting [opioids].”*
- *“This was an example of what a good call looks like … [Dr.] was particularly interested in the RM case study of Marjorie, which generated a robust discussion of opioid naïve patients …”*

124. Purdue (not a defendant herein, but which engaged in the kind of conduct that inspired and informed the conduct of named manufacturer defendants) promoted its drugs for opioid-naïve patients using the deceptive term “first line opioid.” “First line” is



*Purdue opioid promotion from 2015<sup>12</sup>*

a medical term for the preferred first step in treating a patient. Opioids are not an appropriate first line therapy.

125. The Manufacturer Defendants also found vulnerable opioid-naïve patients by targeting prescribers with the least training in the risks of opioids. The Manufacturer

Defendants determined that nurse practitioners, physician assistants, and primary care doctors were especially responsive to sales reps, so the Manufacturer Defendants targeted them to sell more drugs.

### **Osteoarthritis Patients**

126. The Manufacturer Defendants knew that opioids were not appropriate to appropriate to treat nonmalignant pain in non-cancer patients, including patients suffering from osteoarthritis. Opioids are not approved to treat osteoarthritis. For instance, Purdue conducted a single study on osteoarthritis for Butrans, and it failed. Purdue admitted in internal documents that its opioids “are not indicated for a specific disease” and “it is very important that you never suggest to your HCP [health care professional] that OxyContin is indicated for the treatment of a specific disease state such as Rheumatoid Arthritis or Osteoarthritis.”

127. Nevertheless, to meet their business goals, the Manufacturer Defendants trained their sales representatives to mislead doctors by promoting opioids for osteoarthritis.

128. The Manufacturer Defendants also directed their sales reps to use marketing materials that highlight patients with osteoarthritis, even though their drugs were never indicated for that disease.

### **3. The Manufacturer Defendants Deceived Doctors and Patients to Use Higher and Higher Doses**

129. The impetus behind the Manufacturer Defendants’ scheme is as simple as it is nefarious. Enticed by the exponentially greater profits that would result from increases in opioid dose mix, the Manufacturer Defendants deceived prescribing medical practitioners and patients across the nation—and in Ray County—about the risks and benefits of opioids for the long-term treatment of chronic pain. The Manufacturer Defendants dishonestly encouraged these prescribers to provide long-term opioid therapy to patients for whom such treatment was inappropriate, such as patients suffering from

long-term chronic pain due to osteoarthritis. As set forth below, the Manufacturer Defendants' deceptive scheme was wildly successful, effectively increasing the supply of highly addictive prescription opioids, both in the State of Missouri generally and in Ray County, specifically.

130. The Manufacturer Defendants—including, but not limited to, Defendant Endo—also falsely instructed doctors and patients in Missouri communities, including Ray County, that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon “pseudoaddiction”—a made-up, misleading and scientifically unsubstantiated term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Endo, Janssen, Teva, and Purdue. Through aggressive marketing campaigns to Ray County prescribers and patients, the Manufacturer Defendants used the concept of “pseudoaddiction” as a lever to mislead prescribers and their patients into believing that certain warning signs of opioid addiction<sup>32</sup> were neither indicative of “true” addiction nor cause for alarm. To the contrary, the Manufacturer Defendants repeatedly claimed these warning signs were manifestations of undertreated pain, which should be addressed by prescribing more opioids. Importantly, at all times relevant to this action, the Manufacturer Defendants both knew the concept of “pseudoaddiction” was false and yet actively sought to conceal the truth from Ray County’s physicians and patients, sabotaging these prescribers’ ability to protect their patients from opioid addiction and concomitant injuries and make informed decisions about whether or not opioids were appropriate for their patients. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants are described below:

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<sup>32</sup> E.g., demanding more opioids, engaging in manipulative behavior to obtain drugs, requesting specific drugs, hoarding drugs during periods of reduced symptoms, using drugs to treat another symptom, etc.

- a. Cephalon, Endo, and Purdue—owned and controlled by the Sacklers—sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name”, “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online.
- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, sponsored a CME program entitled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in 2011. In a role play exercise, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.
- f. Purdue, which is owned and controlled by the Sacklers, neither of

which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, and Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which states: "Pseudo-addiction describes patient behaviors that may occur when pain is undertreated . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."

131. The medical community now rejects the concept of pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, widely accepted opioid treatment guidelines now provide that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

132. Even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the NY AG, in its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'"<sup>33</sup> Consistent with this testimony, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York.<sup>34</sup>

133. The Manufacturer Defendants also falsely promised prescribers and their

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<sup>33</sup> In the Matter of Endo Health Solutions Inc., *et al.*, Assurance No. 15-228, p. 7, ¶ 23 (NY AG, Mar. 1, 2016), [https://www.ag.ny.gov/pdfs/ENDO\\_AOD\\_030116-Fully\\_Executed.pdf](https://www.ag.ny.gov/pdfs/ENDO_AOD_030116-Fully_Executed.pdf)

<sup>34</sup> *Id.*, p. 15, ¶ 41.e.

patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies would both allow these prescribers to reliably identify and safely prescribe opioids to patients who are predisposed to addiction and be efficacious enough to essentially rule out the risk of opioid addiction (even in the context of long-term opioid therapy). These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after March 21, 2011 are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, sponsored a November 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, has represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

134. Consistent with what the Manufacturer Defendants already knew—but failed to disclose—at all times relevant to this action, opioid treatment guidelines now confirm that the Manufacturer Defendants’ statements were false, misleading, and unsupported at the time they were made by the Manufacturer Defendants. These guidelines note that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—“for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, opioid treatment guidelines now emphasize that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that prescribers “*should not overestimate* the ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

#### **4. The Manufacturer Defendants Peddled Falsehoods to Keep Patients Away from Safer Alternatives**

##### **A. Deception about Quality of Life**

135. The Manufacturer Defendants also steered patients away from safer alternatives with the false claim that its opioids improve patients’ “quality of life.”

##### **B. Deception about Risk of Abuse**

136. In addition to visiting prescribers and pharmacists hundreds of thousands of times, the Manufacturer Defendants distributed thousands of copies of their deceptive publications, including *Providing Relief, Preventing Abuse; Resource Guide for People with Pain; Exit Wounds; Opioid Prescribing: Clinical Tools and Risk Management Strategies; Responsible Opioid Prescribing; Clinical Issues in Opioid Prescribing; and In The Face of Pain.*

#### **5. The Manufacturer Defendants Downplayed Opioids Withdrawal**

137. To downplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that

opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled “Persistent Pain in the Older Adult,” claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur. This publication was available on APF’s website until the organization dissolved in May 2012. Detailers for Janssen have told and continue to tell doctors in Missouri, including Ray County, that their patients would not experience withdrawal if they stopped using opioids.

138. The Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal that, per widely accepted opioid treatment guidelines, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, rapid heartbeat, spontaneous abortion and premature labor in pregnant women, and the unmasking or exacerbating of anxiety, depression, and addiction.

139. The Manufacturer Defendants also grossly understated the difficulty of tapering, particularly after long-term opioid use. Widely accepted opioid treatment guidelines now emphasize that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days.” These guidelines further state that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and

highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. Likewise, regulators have acknowledged the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

140. Some prescribers and many patients across the country and in Missouri communities—including Ray County—relied on the truth of the Manufacturers Defendants’ representations about both the benefits of opioid analgesics and the risks of opioid addiction. Because each of the Manufacturer Defendants willfully or recklessly concealed the truth about their products and knew or should have known their representations were false at the time they were made, Ray County and its citizens are forced to pay the price for Defendants’ misconduct.

## **6. The Manufacturer Defendants Hid the Greater Risks to Patients at Higher Dosages of Opioids**

141. The Manufacturer Defendants were in the best position to know, and in fact did know, that—relative to the general population—the risk of opioid-related death increases exponentially after a patient takes opioids for several consecutive months.

142. Specifically, the Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011, are described below:

- a. Actavis’ predecessor created a patient brochure for Kadian in 2007

that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’ acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

- b. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, and Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have “no ceiling dose” and are therefore the most appropriate treatment for severe pain.<sup>35</sup>
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until “you are on the right dose of medication for your pain.” The website was still accessible online after May 21, 2011.
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased. . . . You won’t ‘run out’ of pain relief.”
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of

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<sup>35</sup> The Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary “upset stomach or sleepiness” and constipation).)

increased opioid dosages.

- f. Through March 2015, another publication from Purdue—which is owned and controlled by the Sacklers—called *In the Face of Pain*, promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue, which is owned and controlled by the Sacklers, sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

143. Through a series of internal strategy presentations and other communications with its sales force and prescriber-accomplices, Manufacturer Defendants aimed to “drive” patients toward higher doses of opioids for longer periods by dramatically increasing the supply. They also sought to increase consumer demand for opioids, namely by offering discounts to patients on their first prescriptions. These discounts proved to be one of the most powerful tactics to keep patients on opioids longer..

**Drive appropriate titration and length of therapy with continuing patients, to maintain total Kg within 2% of forecast**

*Purdue internal strategy presentation from 2012*

144. These claims conflict with the scientific evidence, as confirmed by widely accepted opioid treatment guidelines. These guidelines admonish practitioners and other industry stakeholders that while the “[b]enefits of high-dose opioids for chronic pain are not established,” there are clear “risks for serious harms related to opioid therapy increase at higher opioid dosage.”

145. More specifically, these guidelines explain that “there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.” Opioid treatment guidelines also provide that “there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages.”

146. Because “the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events.” Specifically, the clinical research “appear[s] to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain. In light of this evidence, prescribing clinicians are now advised to “avoid increasing dosages” above 90 morphine milligram equivalents (“MMEs”) each day.

147. Finally, the Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

148. These abuse deterrent formulations (“AD opioids”) are harder (but not impossible) to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Though at all times relevant to this action the Manufacturer Defendants falsely claimed that AD opioids “cannot be crushed,” these claims were conclusively debunked by a study, finding that AD opioids are, in fact, “not impossible” to abuse. They can be defeated—often quickly and easily—by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

149. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, regulators have admonished the Manufacturer Defendants that any communications from the sponsor companies regarding AD properties must be truthful and

not misleading (based on a product's labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.<sup>36</sup>

150. Despite this admonition, the Manufacturer Defendants have made and continue to make misleading claims about the extent to which their AD opioids can prevent or reduce abuse and addiction.

151. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) Endo's petition to approve Opana ER as abuse-deterrant was rejected in 2012; (2) regulators found in 2013 that there was no evidence that Opana ER "would provide a reduction in oral, intranasal or intravenous abuse"; and (3) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo's advertisements for the 2012 reformulation of Opana ER falsely claimed that Opana ER could not be crushed, creating the impression that the drug was more difficult to abuse. On information and belief, detailers for Endo continue to reiterate these false statements to prescribers and patients across the country and in Missouri communities, including Ray County.

152. In the 2016 settlement with the NY AG, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The NY AG found those statements false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

153. Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in 2017, regulators requested that Endo withdraw Opana ER from the market.

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<sup>36</sup> *Ibid.*

154. Likewise, Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, has engaged and continues to engage in deceptive marketing of its AD opioids—*i.e.*, reformulated Oxycontin and Hysingla—since at least May 21, 2011. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Missouri prescribers report that detailers from Purdue have regularly used the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate those products from their competitors. Specifically, these detailers: (1) claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (2) claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue’s AD opioids are “safer” than other opioids; and (4) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

155. These statements and omissions by Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, are false and misleading and conflict with or are inconsistent with the approved label for Purdue’s AD opioids—which indicates that abusers do seek them because of their high likability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

156. A 2015 study also shows that many opioid addicts are abusing AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue’s AD opioids

was reduced, those addicts simply shifted to other drugs such as heroin.<sup>37</sup> Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.

157. Similarly, widely accepted clinical guidelines for opioid therapy expressly state that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” Regulatory agencies have further reported that their staff could not find “any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”<sup>38</sup>

158. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, the Manufacturer Defendants are using these claims in a spurious attempt to rehabilitate their image as responsible opioid manufacturers. Second, these claims are falsely targeting doctors' concerns about the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids—which are far more expensive than other opioid products even though they provide little or no additional benefit.

159. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by the Manufacturer Defendants successfully convinced doctors and

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<sup>37</sup> Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin*, 72.5 JAMA Psychiatry, 424-30 (2015).

<sup>38</sup> Perrone, *Drugmakers push profitable, but unproven, opioid solution* (Dec. 15, 2016), <https://publicintegrity.org/state-politics/drugmakers-push-profitable-but-unproven-opioid-solution/>.

patients to discount those risks, including doctors and patients in Missouri and Ray County.

## **7. The Manufacturer Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy**

160. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. However, as the widely accepted clinical guidelines for opioid therapy now make clear that there is “insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain.”

161. In fact, these guidelines found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq$  6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

162. Likewise, regulators recognize the lack of evidence to support long-term opioid use. In 2013, for instance, one regulator stated it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.” Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. On information and belief, not only have the Manufacturer Defendants failed to correct these false and misleading claims, they continue to make them today in Missouri and in Ray County.

163. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients’ function and quality of life. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by the Manufacturer Defendants after May 21, 2011 are described below:

- a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve “stress on your body and your mental health,” and help patients enjoy their lives.

- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009)—which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’”
- d. Purdue, which is owned and controlled by the Sacklers, neither of which/whom are defendants in this case, but which engaged in the kind of conduct that inspired and informed the conduct of other named manufacturer defendants, ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients’ function.
- e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo, Cephalon and Purdue—owned and controlled by the Sacklers—taught that relief of pain by opioids, by itself, improved patients’ function.
- f. Purdue, which is owned and controlled by the Sacklers, and Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids “give [pain patients] a quality of life we deserve.”
- g. Endo’s NIPC website painknowledge.com claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and

improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

- i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.”
- j. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that government statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Since at least May 21, 2011, sales representatives for Endo, Teva and Janssen’s sales representatives have conveyed and continue to convey to prescribers in Missouri, including in Ray County, the message that opioids will improve patient function.

164. These claims find no support in the scientific literature. Regulators as well as industry stakeholders have made this clear for years. Most recently, widely accepted clinical guidelines for opioid concluded that “there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely.”

As illustrated below, this conclusion is reinforced throughout these guidelines:

- “*No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . .*”
- “*Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.*”
- “[*E*vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

165. Industry guidelines for opioid therapy also note that the risks of addiction

and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

166. Consistent with these guidelines, regulators have also repudiated Defendants’ claim that opioids improved function and quality of life. In 2010, for instance, regulators warned Actavis, in response to its advertising described above, that “[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.” And in 2008, regulators sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

167. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the long-term treatment of chronic pain. For example, the Manufacturer Defendants, before and after May 21, 2011, have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene widely accepted clinical guidelines for opioid therapy as well as pronouncements by and guidance from regulators based on the scientific evidence. Indeed, in 2013, the labels for ER/LA opioids and IR opioids were changed to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” An identical change was made to the labels of IR opioids in 2016. And widely accepted clinical guidelines regarding opioid therapy expressly state that NSAIDs—not opioids—

should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

### **8. The Manufacturer Defendants Engaged in Other Unlawful and Unfair Misconduct**

168. For over a decade, the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail- and prescriber-levels. Using—*inter alia*—their extensive networks of sales representatives and private databases containing years of prescribing data, the Manufacturer Defendants had and continue to have intimate knowledge of the prescribing practices of thousands of prescribing clinicians in Missouri, including clinicians in Ray County.

169. In stark contrast to repeated admonitions from regulators regarding the Manufacturer Defendants’ “obligation to design and operate a system to disclose . . . suspicious orders of controlled substances” and to inform regulators “of suspicious orders when discovered,” the Manufacturer Defendants have improperly leveraged their respective sales networks and prescribing databases to identify and improperly increase marketing efforts to prescribers who have inappropriately prescribed the Manufacturer Defendants’ opioids, without reporting these prescribers to the appropriate authorities. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health Services, said in a Los Angeles Times article, “[a]ny drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s lives has a responsibility to report it.”

170. For instance, Defendant Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also

found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids after May 21, 2011, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

171. In 2000, Mylan agreed to pay \$100 million to resolve allegations that it conspired to deny its competitors certain necessary ingredients to manufacture several widely-prescribed medications, including treatments for opioid use disorder and opioid addiction. As alleged in petitions filed by thirty-two State Attorneys General and the District of Columbia, Mylan's conduct caused substantial price increases in, and improperly limited the supply of, these treatments.

In 2013, West-Ward was forced to pay penalties for shirking the company's legal obligation to make timely payments to drug discount programs that provide vulnerable patient population with affordable access to pharmaceuticals, and also agreed to pay \$10,000,000 to resolve allegations that West-Ward had also been inflating prescription drug prices since 1995, effectively overcharging some of its most vulnerable patient populations.

172. In addition, Manufacturer Defendant Hospira has been cited by regulatory agencies for both failing to operate its manufacturing facilities in compliance with basic health and safety guidelines intended to prevent microbiological contamination of Hospira's products—including opioids—and for failing to investigate known defects in its products.

173. Despite the clear consequences for their misconduct, for years the Manufacturer Defendants' sales representatives have pressed prescribing clinicians to prescribe their opioids, offering various gifts, rewards and/or other financial incentives to prescribers, to persuade these clinicians to help the Manufacturer Defendants facilitate their widespread deception about the risks and benefits of opioids for the long-term treatment of chronic pain. Indeed, on information and belief, the Manufacturer Defendants' misconduct

is ongoing as they continue to profit from the prescriptions of such prolific prescribers in Missouri, including in Ray County.

**F. Although the Manufacturer Defendants Knew That Their Marketing of Opioids Was False and Misleading, They Fraudulently Concealed Their Misconduct**

174. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. Regulators warned the Manufacturer Defendants of this. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, regulators have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and several Manufacturer Defendants have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Petition in New York.

175. Moreover, at all times relevant to this Petition, the Manufacturer Defendants fraudulently concealed their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

176. The Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and “educational” materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Other Manufacturer Defendants, such as Janssen, ran similar websites that masked their own direct role.

177. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Manufacturer Defendants’ deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiff.

178. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants’ industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

**G. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Manufacturer Defendant Has Created or Assisted in the Creation of a Public Nuisance in Ray County**

**1. The Manufacturer Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in Ray County**

179. The Manufacturer Defendants' misrepresentations deceived and continue to deceive doctors and patients in Ray County about the risks and benefits of long-term opioid use. Studies also reveal that some doctors and many patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. No doubt, Missouri residents in treatment for opioid addiction, including residents of Ray County, were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

180. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

181. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices caused and continue to cause doctors and other clinicians in Ray County to prescribe opioids for the long-term treatment of chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent the Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, these doctors would not have prescribed as many opioids to as many

patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

182. The Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices also caused and continue to cause patients in Missouri, including patients in Ray County, to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them. The Manufacturer Defendants' deceptive marketing and their unlawful and unfair business practices have caused and continue to cause the prescribing and use of opioids to explode in Ray County.

183. The Manufacturer Defendants' deceptive marketing of the abuse-deterrant properties of their opioids during the past few years has been particularly effective, including in Ray County. Such deceptive marketing has created the false impression among pain specialists and other prescribers that Defendants' AD opioids are appropriate for the long-term treatment of chronic pain, which in turn has increased the number of prescriptions for these Defendants' AD opioids. Although sales of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in opioid sales revenue in 2015).

184. The dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in the Manufacturer Defendants' spending on their deceptive marketing scheme. The Manufacturer Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to \$288 million.

**2. By Causing an Explosion in Opioid Prescriptions and Use, the Manufacturer Defendants Have Created or Assisted in the Creation of a Public Nuisance in Ray County**

185. The escalating number of opioid prescriptions written by doctors who were

deceived by the Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Missouri, including in Ray County.

186. Representing regulators in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."

187. In August 2016, the Surgeon General published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

188. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, one regulator explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, regulators have concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

189. Contrary to the Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

190. As regulators observed in 2016, the opioid epidemic is getting worse, not better. The overprescribing of opioids for chronic pain caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Missouri who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. From 2006 to 2016, there was a 538% increase in reported cases of NAS in Missouri alone. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts.

191. The Manufacturer Defendants' creation, through false and misleading advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed Ray County. The Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

192. The rise in opioid addiction caused by the Manufacturer Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year previously abused prescription opioids.

193. Many patients who become addicted to opioids will lose their jobs. Some will lose their homes and their families. Some will get treatment and fewer will

**Number of Infants Born with NAS and Percent Increase from 2006**



successfully complete it; many of those patients will relapse, returning to opioids or some

other drug. Of those who continue to take opioids, some will overdose—some fatally, some not. Others will die prematurely from related causes—falling or getting into traffic accidents due to opioid-induced somnolence; dying in their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit drug transactions; or dying from opioid-induced heart or neurological disease.

194. Absent each Manufacturer Defendants' deceptive marketing scheme and their unlawful and unfair business practices, the public health crisis caused by opioid misuse, abuse, and addiction in Ray County, would have been averted or much less severe.

195. These harms in Ray County, caused by the Manufacturer Defendants' deceptive marketing schemes and unlawful and unfair business practices are a public nuisance because they are an offense against the public order and economy and violates the public's right to life, health, and the use of property, while, at the same time, annoys, injures, endangers, renders insecure, interferes with, or obstructs the rights or property of the whole community, or neighborhood, or of any considerable number of persons.

### **3. The Manufacturer Defendants Knew and Should Have Known That Their Deceptive Marketing Schemes Would Create or Assist in the Creation of This Public Nuisance in Ray County**

196. The Manufacturer Defendants knew and should have known about these harms that their deceptive marketing and unlawful and unfair business practices have caused and continue to cause in Ray County. The Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. The Manufacturer Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew—and, indeed, intended—that their misrepresentations would persuade doctors in Ray County to prescribe, and patients in Ray County to use, their opioids for the long-term treatment of chronic pain.

**4. The Manufacturer Defendants' Conduct and Role in Creating or Assisting in the Creation of the Public Nuisance Is Not Excused by the Actions of any Third Parties**

197. The Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. Government approval of opioids for certain uses did not give the Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, the Manufacturer Defendants' misrepresentations were directly contrary to pronouncements by and guidance from regulators based on the medical evidence and their own labels.

198. Likewise, the Manufacturer Defendants' causal role was not broken by the involvement of healthcare providers. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors and other prescribing clinicians could rely on for information and prevented them from making informed treatment decisions. The Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

**H. The Manufacturer Defendants' Fraudulent Marketing Has Led To Record Profits**

199. While the use of opioids has taken an enormous toll on Ray County and its citizens, the Manufacturer Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like the Manufacturer Defendants. Indeed, financial information indicates that each Manufacturer Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

**I. John Kapoor and Michael Babich Led Insys's Misconduct**

200. Missouri laws against both the creation of a public nuisance as well as unfair and deceptive conduct in commerce applies to individuals regardless of whether they are

officers, directors, or employees. Holding individuals personally liable for their misconduct does not require piercing a corporate veil. Individuals are personally liable if: (a) they participated in the misconduct; or (b) they knew about the misconduct and failed to stop it; or (c) they should have known about the misconduct and they failed to stop it.<sup>39</sup> In this case, the Individual Defendants John Kapoor and Michael Babich made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected many millions of dollars from the deception.

201. John Kapoor (“Kapoor”), the founder and majority owner of Insys, and Michael Babich (“Babich”), the former CEO and President of Insys, led a nationwide conspiracy to profit using bribes and fraud to cause the illegal distribution of Subsys.

202. Kapoor and Babich conspired to bribe practitioners in various states, including in Missouri, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, many of whom were not diagnosed with cancer, and therefore did not need Subsys.

203. Kapoor and Babich also conspired to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when it was prescribed for non-cancer patients. They achieved this goal by setting up a “reimbursement unit” which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

204. Kapoor and Babich fueled the opioid epidemic by paying doctors to needlessly prescribe Subsys for patients who did not need it, and without complying with Missouri law, thus putting patients at risk and contributing to the current opioid crisis. Kapoor and Babich committed fraud, placing profit before patient safety, to sell a highly potent and addictive opioid.

**J. Distributor Defendants' Violation of Duty**

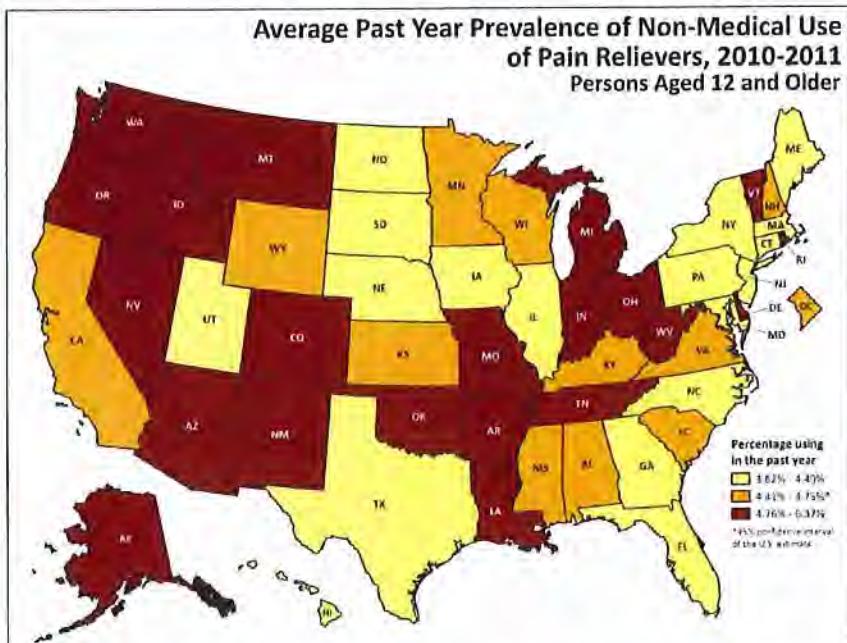
205. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

206. Specifically, under Mo. Rev. Stat. § 195.050.6 all “[e]very person registered to manufacture, distribute or dispense controlled substances”—*i.e.*, “Registrants”—are obligated to design and operate a system to disclose to the registrant suspicious orders of controlled substances, especially opioids. Each of the Distributor Defendants is a registrant for purposes of this section and, therefore, must satisfy certain reporting requirements of any and all “suspicious orders.” Orders of controlled substances that are either unusual in size or frequency, or otherwise substantially deviate from a normal pattern, qualify as “suspicious orders.”

**K. Distributor Defendants Knew or Should Have Known They Were Facilitating Widespread Opioid Diversion**

207. Opioid diversion in the supply chain has always been a widespread problem and has been highly publicized. Numerous publications from regulators and professional health associations have highlighted the epidemic rate of opioid abuse and overdose rates in Missouri and Ray County, as well as throughout the United States.

208. Prescription drug abuse is one of the fastest-growing drug problems in the United States, particularly in Missouri. In 2010-2011, 4.76%-6.37% of Missourians engaged in non-medical use of pain relievers.



209. To combat the problem of opioid diversion, regulators have provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

210. Since 2006, regulators have conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders). The distributors were provided with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. These materials pointed out “red flags” distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

211. For years, regulators have hosted conferences to provide distributors with updated information about diversion trends and regulatory changes that affect the drug

supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors—including AmerisourceBergen and Cardinal Health—attended at least one of these conferences. The conferences allowed distributors to ask questions and raise concerns and request clarification on policies and procedures intended to prevent opioid diversion.

212. Likewise, regulators have participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (“HDMA”), now known as the Healthcare Distribution Alliance (“HDA”), an industry trade association for wholesalers and distributors. Regulators have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.<sup>40</sup> (HDMA, “Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,” (2008).

213. On September 27, 2006 and again on December 27, 2007, regulators sent letters to all relevant opioid distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion. These letters reminded these distributors that they were required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. These letters explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling.

214. Again, in 2007 regulators sent a follow-up letter to all relevant opioid

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<sup>40</sup> See, e.g., HDA.org, Issues in Distribution, *Prescription Drug Abuse and Diversion* (2018) (describing various resources “address[ing] the industry’s approach to countering diversion and ensuring the safe supply of medicines to licensed entities across the supply chain”), <https://www.hda.org/issues/prescription-drug-abuse-and-diversion>.

distributors, providing guidance and reinforcing the legal requirements outlined in prior correspondence. The letter reminded distributors that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised distributors that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the distributors from legal responsibility.

215. The Distributor Defendants were also on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled “Reporting Suspicious Orders and Preventing Diversion of Controlled Substances” that stressed the critical role of each member of the supply chain in distributing controlled substances.

216. Opioid distributors themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking actions to curb the opioid epidemic.

217. For example, a Cardinal executive recently claimed that it uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

218. These assurances, in addition to obligations imposed by law, show that Distributor Defendants understand and have undertaken a duty to protect the public against diversion from their supply chains, and to curb the opioid epidemic.

219. However, despite these statements and duties, Distributor Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by government agencies, including actions by

regulators.

220. In 2008, Cardinal Health paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal Health reached an administrative settlement to resolve allegations of opioid diversion between 2009 and 2012 in multiple states. Even more recently, in December 2016, Cardinal Health settled similar allegations of opioid diversion, misuse, abuse, overdose and death. During the investigation of Cardinal Health, evidence was discovered that Cardinal Health's own investigator warned the company against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Instead of heeding the investigator's warning, Cardinal Health increased its opioid shipments to this pharmacy by almost 2 million doses of oxycodone in just one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

221. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against the diversion of particular controlled substances into non-medically necessary channels. It has been reported that AmerisourceBergen has been subpoenaed for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

222. Although these Distributor Defendants have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.

223. Plaintiff does not bring causes of action based on violations of federal statutes and regulations. However, the existence of these complicated regulatory schemes shows Defendants' intimate knowledge of the dangers of diversion of prescription opioids

and the existence of a thriving illicit market for these drugs. The Defendants breached their duties to Plaintiff despite this knowledge and longstanding regulatory guidance of how to deter and prevent diversion of prescription opioids.

**L. The Pharmacy-Distributor Defendants Understood But Violated Their Duties**

224. Pharmacy-Distributor Defendants, Walmart and PBA, earned enormous profits by flooding the country, including Ray County, with prescription opioids. They gained unique knowledge of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Rather than act to stem the flow of opioids into communities like Ray County, they participated in and profited from the oversupply.

225. The Pharmacy-Distributor Defendants have publicly acknowledged the risks of opioids and assured the public that public health and safety are their highest priorities. However, their public representations belied their own wrongdoing that contributed to the opioid epidemic. The Pharmacy-Distributor Defendants have recklessly or negligently permitted opioid diversion to occur, engaging in a consistent pattern of illegally distributing prescription opioids, while failing to uphold their duty to report such suspicious orders, and—on information and belief—each of the Pharmacy-Distributor Defendants is a top dispenser of opioids to Ray County patients and has committed and continues to commit serious and flagrant violations of their duties under Missouri law regarding—*inter alia*—recordkeeping and dispensing opioids to Ray County patients.

226. For instance, in 2017, Walmart acknowledged the need for a “solution to the [opioid] epidemic” and noted the epidemic has “devastated so many families and communities across America.”<sup>41</sup> However, on information and belief, Walmart has also

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<sup>41</sup> Press Release, Walmart, *Walmart Supports the State of Emergency Declaration on Opioids* (Oct. 26, 2017), <https://news.walmart.com/2017/10/26/walmart-supports-state-of-emergency-declaration-on-opioids>.

paid settlements to resolve allegations of violations in connection with Walmart's distribution of opioids to various states, including Missouri.

**M. Each of the Defendant's Misconduct Has Injured and Continues to Injure Ray County and Its Citizens**

227. In addition to the significant social costs associated with illicit drug use, Defendants' predatory and willful misrepresentations in manufacturing, marketing and/or distributing opioids have imposed significant tax-based economic damages on Ray County, including tax revenue expended incident to providing various public services that Ray County is required to provide to its citizens under Missouri law, including healthcare- and crime-related costs. These revenues would not have been expended but for the opioid crisis that Defendants willfully and foreseeably caused in Missouri, generally, and in Ray County, specifically.

228. As Defendants' opioids continue to wreak havoc on communities across the country and in Missouri, including Ray County, citizens are becoming incapacitated by and/or dying from opioids. Ray County has also been deprived of the benefits these citizens would have conferred to their community but for Defendants' wrongful conduct. Ray County has lost both the productivity of Ray County's citizens who have been hospitalized, incarcerated, killed, or otherwise incapacitated by opioids as a result of Defendants' deception described in this Petition, including the collection of property and/or sales taxes these citizens would have paid had Defendants simply told the truth about the risks and benefits of opioids for the long-term treatment of chronic pain.

**1. Tax Revenue Expended—Healthcare-Related Costs**

229. Since 2010 to present day, drugs kill more Missourians than motor vehicle accidents with 70% of drug overdose deaths attributed to opioid abuse.<sup>42</sup>

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<sup>42</sup> Missouri Hospital Association, *A Dangerous Intersection: Drug Overdose Fatalities Surpass Motor Vehicle Deaths* (2018), [https://www.mhanet.com/mhainages/opioid/MVA\\_v\\_Opioids/A\\_Dangerous\\_Intersection.pdf](https://www.mhanet.com/mhainages/opioid/MVA_v_Opioids/A_Dangerous_Intersection.pdf).

230. While Defendants reaped billions of dollars in profits from their deceptive conduct, Ray County has suffered—and continues to suffer—irreparable damage in the form of increased healthcare-related costs, which Missouri law requires that Ray County pay, to protect the health and safety of its citizenry. Ray County would not have incurred these costs had Defendants not concealed the dangers (and misrepresented the benefits) of the relevant opioids.

231. In particular, each of the Defendants has directly and proximately caused Ray County to divert precious tax dollars and local resources from Ray County's general and special revenue funds, in order to address its citizens' ever-increasing need for county-funded, opioid-related health services, including hospital and emergency services.

**(a) Emergency Medical Treatment—Opioid-Related Emergencies**

232. Between 2006 to 2015, Missouri saw a 138% increase in hospitalizations and emergency department visits due to opioid misuse or abuse.<sup>43</sup> Opioids have a significant impact upon Missouri's medical care system due to the volume of encounters involving opioids, and the costs of these encounters. While the full economic burden of opioids upon the healthcare system is difficult to precisely calculate, a reasonable measure may be derived using hospital reported charges provided by the Hospital Industry Data Institute. In 2016, using this approach, the cost of 921 opioid overdose deaths was an estimated \$12.1 billion.<sup>44</sup> Thus, in 2016, the average cost per opioid-related death amounts to \$13,029,315.96. In 2017, opioid use and overdose deaths cost the state of Missouri more

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<sup>43</sup> Missouri Hospital Association, *Trends in Hospital Utilization for Opioid Overuse and Drug-Dependent Newborns in Missouri*, p. 4 (2016), [https://www.mhanet.com/mhainfo/images/opioid/NAS\\_Research.pdf](https://www.mhanet.com/mhainfo/images/opioid/NAS_Research.pdf).

<sup>44</sup> M. Reidhead, *The Economic Cost of the Opioid Epidemic in Missouri*, Missouri Hospital Association, p. 2 (Jan. 2018), [https://www.mhanet.com/mhainfo/images/HIDIHealthStats/Feb2018HealthStats\\_Special\\_OpioidsEconomy.pdf](https://www.mhanet.com/mhainfo/images/HIDIHealthStats/Feb2018HealthStats_Special_OpioidsEconomy.pdf).

than \$14 billion, or \$38.4 million a day.<sup>45</sup>

233. As the number of opioid-related hospital encounters in Ray County has ballooned, the costs of treatment and supplies have also increased. This increase has strained—and continues to strain—Plaintiff's coffers, which provide the financial resources needed to respond appropriately to an increasingly large demand for opioid-related medical services in the County including costs for furnishing necessary supplies such as providing Narcan and Naloxone, specialized training, law enforcement and public safety staff.

## **2. Tax Revenue Expended—Crime-Related Costs**

234. In addition to imposing on Plaintiff increasing healthcare-related costs, Defendants' scheme has also damaged Ray County in the form of increased criminal justice costs, including those associated with opioid-related arrests, investigations and other local services provided by the sheriff's office. Funds necessary to maintain the day-to-day operating expenses and equipment for these programs come from Plaintiff's tax revenues, including Plaintiff's revenues from Plaintiff's privilege (sales) taxes and property taxes.<sup>46</sup>

235. Because Plaintiff finances the operation of the Ray County Sheriff's Office through the county's coffers, the increased burden on the Ray County Sheriff's Office resulting from Defendants' misconduct has likewise damaged Plaintiff.

### **(a) Opioid-Related Arrests and Investigations**

236. The effects of Defendants' deceptive marketing and distribution scheme have further impacted Plaintiff by creating various public nuisances—including public health and safety hazards—which Plaintiff is obligated to abate. Plaintiff has dedicated

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<sup>45</sup> Lily Lieberman, *Missouri's costs from opioid crisis exceed \$14B*, Kansas City Business Journal (Mar. 28, 2019), <https://www.bizjournals.com/kansascity/news/2019/03/28/missouri-s-costs-from-opioid-crisis-exceed-14b.html>.

<sup>46</sup> *Id.*

substantial tax dollars to maintain the public safety and mitigate the incidence of drug and property crimes. Many of these drug and property crimes are committed by opioid addicts who are both actively looking to feed their addictions, as well as suffering from serious medical conditions typically associated with the spread opioid abuse, such as Hepatitis B and C, HIV, sexually transmitted diseases and methicillin-resistant staphylococcus aureus (“MRSA”), among other conditions. Specifically, the Ray County Sheriff’s Office has expended funds and exerted effort to investigate and respond to opioid-related calls and crimes. From 2015 to 2017, there were approximately 788 reported drug-related arrests in Ray County.<sup>47</sup>

237. From 2012-2016, there were at least 137 recorded emergency room visits due to opioid abuse by Ray County residents, many of which required the dedicated time of several sheriff’s department officers to perform various tasks, including—but not limited to—investigations, arrests, bookings, report writing, evidence impounding, scene security and follow up time.<sup>48</sup>

238. Because funds essential to the operation of the Ray County Sheriff’s Office come from the County’s coffers, the increased burden on the Ray County Sheriff’s Office resulting from Defendants’ misconduct has likewise damaged Plaintiff.

239. In abating the opioid nuisance to protect the health and safety of citizens of Ray County, Plaintiff has suffered pecuniary damages, proximately caused by Defendants’ misrepresentations and omissions of material fact.

#### **(b) Jail Services**

240. Increases in jail services costs may also be attributed to Plaintiff’s efforts to

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<sup>47</sup> Missouri Department of Mental Health, Substance Use and Mental Health Indicators, 2018 Status Report on Missouri’s Substance Use and Mental Health, <https://dmh.mo.gov/ada/countylinks/documents/indicator-ray.pdf>.

<sup>48</sup> Bureau of Health Care Analysis and Data Dissemination, Missouri Department of Health and Senior Services, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-16.pdf>.

abate the ongoing public nuisance that the Defendants created and/or exacerbated in Ray County. From 2016 to 2018, there were 119 drug-related prison admissions in Ray County.<sup>49</sup> During that same time period, 299 Ray County residents were on drug-related parole or probation.<sup>50</sup>

### **(c) Court Costs**

241. As the Defendants' misconduct has continually frustrated Plaintiff's efforts to protect the health and safety of its citizenry, Ray County has allocated and continues to allocate substantial sums to finance the operation of juvenile court referrals. From 2015 to 2017, there were 35 drug-related offenses committed by juveniles in Ray County.<sup>51</sup> For that same period, there were 6 juvenile out-of-home placements due to parental drug use.<sup>52</sup>

242. As the utilization of these services by Ray County citizens has increased over the years of the opioid crisis, so too have Plaintiff's allocations to maintain these important county-funded services and maintain the health and safety of Plaintiff's citizens.

### **3. Tax Revenue Forgone**

243. Tax revenue forgone is a consequence of incapacitation. The principal events associated with incapacitation include specialty treatment, hospitalization, and death. As a result of such incapacitation, the citizens of Ray County who became addicted to Defendants' opioids are unable to work or contribute to Ray County's financial health through sales, property, and other taxes.

244. The lost tax revenue attributable to these patients is especially significant for Plaintiff, as the vast majority of such patients would—but for their addiction—be

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<sup>49</sup> 2018 Status Report on Missouri's Substance Use and Mental Health, <https://dmh.mo.gov/ada/countylinks/documents/indicator-ray.pdf>.

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

productive members of Plaintiff's community.

245. The opioid epidemic and public nuisance that resulted from Defendants' deceptive strategy continues to frustrate Plaintiff's ability to recover from the crisis.

246. Leading up to and following the peak years of the opioid crisis, Plaintiff's total tax revenue per capita has been largely affected. As set forth below, Defendants' willful, dishonest scheme made it much more difficult—and significantly more expensive—for Plaintiff to ameliorate its tax-related damages associated with the incapacitation of both its citizens and others who either died in Ray County, or were incapacitated in Ray County.

#### **(a) Hospitalization**

247. Patients who are hospitalized in connection with opioid-related emergencies are likewise unable to contribute to the County's financial health with their labor or through the payment of taxes. In 2005, 10,847 Missourians visited hospital inpatient or emergency departments for treatment related to opioid overuse. By 2014, this rate increased by 137% with 25,711 visits and continues to rise.<sup>53</sup> From 2012-2016, approximately 40,213 Missouri residents visited the Emergency Room due to opioid abuse.<sup>54</sup> Moreover, according to government estimates, opioid-related hospital stays were consistently longer than those attributable to both hallucinogens and stimulants, including cocaine and methamphetamine. Longer hospital stays are usually more expensive and lead to larger losses of productivity for the hospitalized patient.

248. Due to Ray County's small population size and rural geography, Ray County

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<sup>53</sup> Missouri Hospital Association, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015), [https://www.mhanet.com/mhainages/HIDIHealthStats/Opioids\\_HealthStats\\_1015.pdf](https://www.mhanet.com/mhainages/HIDIHealthStats/Opioids_HealthStats_1015.pdf)

<sup>54</sup> Bureau of Health Care Analysis and Data Dissemination, Missouri Department of Health and Senior Services, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-16.pdf>

residents have limited access to emergency medical care resources. Ray County Memorial Hospital, located within Ray County, is the County's only full-service hospital with an emergency department. Beyond Ray County Memorial Hospital, the nearest hospitals with emergency departments are located outside of Ray County and are at least an hour away. Because Ray County does not have the funding for specialty healthcare-related services and programs related to opioid abuse for its residents, Ray County residents continue to suffer from preventable opioid overdoses at their own expense, contributing to the loss of productivity for the hospitalized patient. From 2012-2016, there were at least 137 recorded emergency room visits due to opioid overdoses in Ray County.<sup>55</sup> In 2015 alone, Ray County residents reported at least 6 drug-related hospitalizations and 31 drug-related emergency room visits.<sup>56</sup>

#### **(b) Death**

249. According to government estimates, some 50,000 Americans died from an opioid overdose in 2016—*i.e.*, 137 people per day, and roughly one person every 12 minutes.<sup>57</sup> The emotional devastation caused by Defendants' despicable actions is impossible to quantify; however, as described above, the purely economic consequences of the opioid epidemic can and have been successfully tracked in terms of lives, lost productivity, healthcare, criminal justice and other costs. In fact, Missouri's years of potential life lost ("YPPL") has been consistently higher than the U.S. average for the past

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<sup>55</sup> Bureau of Health Care Analysis and Data Dissemination, Missouri Department of Health and Senior Services, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-16.pdf>.

<sup>56</sup> Missouri Department of Mental Health, Behavioral Health Profile, Ray County (2018), <https://dmh.mo.gov/docs/ada/commprofile2018-ray.pdf>.

<sup>57</sup> Money.com, *Here's What I Would Cost to Fix the Opioid Crisis, According to 5 Experts* (Nov. 27, 2017), <http://money.com/money/5032445/cost-fix-opioid-crisis/>.

five years due to opioid abuse.<sup>58</sup> Accordingly, in 2017, President Donald Trump’s Council of Economic Advisers estimated that the economic consequences to the nation of the opioid drug epidemic cost the United States \$504 billion in 2015 alone, prompting the President to declare the opioid crisis a nationwide public health emergency.

250. Undoubtedly, Plaintiff has been affected by the opioid crisis. From 2013 to 2017, approximately 3,827 Missourians died from opioid-related intoxication causes.<sup>59</sup> During that same period, at least 9 Ray County individuals died from opioid-related intoxication causes, who would not have died but for the Defendants’ misconduct as described in this Petition.<sup>60</sup>

#### **WAIVER OF CERTAIN CLAIMS FOR RELIEF**

251. Ray County expressly disclaims and waives any and all right to recovery, whether financial, injunctive, or equitable, relating to or arising out of the distribution by any person of any product, or the provision of any service, pursuant to McKesson Corporation’s (“McKesson”) Pharmaceutical Prime Vendor Contract (“PPV Contract”) with the United States Department of Veteran Affairs. Specifically, Ray County expressly disclaims and waives any and all right to recover against any of the Defendants under the terms and conditions of any PPV Contract or any similar contract.

252. Ray County further commits that it will not, in any forum, rely on or raise the PPV Contract in connection with its allegations and/or prosecution in this matter.

253. Ray County agrees that should Defendants present evidence sufficient for the trier of fact to determine that Ray County’s injuries were caused, in whole or in part, by

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<sup>58</sup> Bureau of Vital Statistics, Missouri Department of Health and Senior Services and WONDER, Centers for Disease Control and Prevention, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-29.pdf>.

<sup>59</sup> Bureau of Vital Statistics, Missouri Department of Health and Senior Services, <https://health.mo.gov/data/opioids/pdf/opioid-dashboard-slide-4.pdf>.

<sup>60</sup> *Id.*

the distribution of products or provision of services through the PPV, Defendants are entitled to a reduction of their liability proportionately by the extent to which the trier of fact determines that any injury to Ray County was caused by goods or products distributed and/or services provided through the PPV.

**V. CAUSES OF ACTION**

**COUNT I**

**Public Nuisance**

**(Against All Defendants)**

254. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

255. Ray County brings a public nuisance action under Missouri common law, which provides that counties in Missouri have the power to suppress all nuisances, which are—or may be—injurious to the health and welfare of inhabitants as well as to recover costs associated with the nuisance.

256. In Missouri, a public nuisance is an offense against the public order and economy of that state and violates the public's right to life, health, and the use of property, while, at the same time, annoys, injures, endangers, renders insecure, interferes with, or obstructs the rights or property of the whole community, or neighborhood, or of any considerable number of persons. Public rights include the public health, the public safety, the public peace, the public comfort, or the public convenience.

257. Each Defendant has caused actual harm to Plaintiff because of the products manufactured, marketed, and distributed through deceptive practices and conduct resulting in a public nuisance often referred to as the opioid epidemic. The conduct of each Defendant involves a significant interference with the public's health, safety, peace, and comfort. Each Defendant's conduct giving rise to the opioid crisis is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has

reason to know, has a substantial effect on the entire community.

258. Additionally, or in the alternative, Defendants engaged in an agreement and conspiracy to illicitly market and distribute opioids in Missouri and/or not report illegal diversions of opioids within Ray County. Defendants are jointly and severally liable for the public nuisance. For example, and as previously described in this Petition, Defendants funded organizations like the American Pain Association to mislead doctors and the public about the safety and efficacy of prescription opioids.

259. The Defendants acted in concert with one another pursuant to an agreement with a common intent and purpose that has resulted in a public nuisance and has directly contributed to Plaintiff's damages.

260. Plaintiff further alleges that each Defendant is jointly and severally liable for the public nuisance in Ray County because their conduct has caused an offense against the public order, threatens Plaintiff's economy, and violates the public's right to life and health.

261. Defendants, acting in concert and/or in conspiracy with one another, intentionally, unlawfully, and/or recklessly manufactured, marketed, and distributed prescription opioids which Defendants knew, or reasonably should have known, would be improperly diverted, causing widespread distribution of prescription opioids in and/or to Ray County resulting in: addiction and abuse, an elevated level of crime, death and injuries to the citizens of Ray County at the expense of Plaintiff, a higher level of fear, discomfort and inconvenience within Ray County, and direct and indirect costs to Plaintiff.

262. Defendants, acting in concert and/or in conspiracy with one another, intentionally, unlawfully, and/or recklessly deceived doctors and patients about the risks and benefits of prescription opioids for the treatment of chronic pain, sabotaging practitioners' and prescribers' ability to protect their patients from opioid-related injuries and conditions.

263. Defendants have unlawfully and/or intentionally caused and permitted highly addictive drugs under their control to be diverted in a way that injures Ray County's

citizenry at the expense of Plaintiff.

264. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion, which is illegal. Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders, which has created an opioid epidemic throughout Missouri and, specifically, within Ray County.

265. The conduct of each Defendant is of a continuing nature and has produced a permanent or long-lasting effect that, as each Defendant knows or has reason to know, has and continues to have a substantial effect on the entire community.

266. As a direct and proximate result of Defendants' conduct, Plaintiff's citizens have suffered from physical and mental injuries, including death, at Plaintiff's expense. The full extent of the destruction caused by Defendants' misrepresentations about the risks and benefits of these drugs has not yet been quantified because the loss of human life, the resources devoted to administering and trying to save lives, and the costs incurred by Plaintiff are far reaching.

267. This injury to the public includes, but is not limited to (a) widespread dissemination of false and misleading information regarding the risks, benefits, superiority and appropriateness of opioids for the long-term treatment of chronic pain; (b) distortion of the medical standard of care for treating chronic pain, resulting in a pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on Ray County families and communities; (d) increased healthcare costs for individuals, families, employers, and Ray County; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, illicit market for opioids; and (g) greater demand for emergency services and law enforcement paid for by Ray County.

268. Defendants knew or should have known that their promotion of opioid use

would create a public nuisance.

269. Defendants' actions were, at least, a substantial factor in opioids becoming widely available and widely used. Absent Defendants' actions and omissions described in this Petition, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse and addiction that now exists in Ray County would have been averted.

270. The health and safety of Ray County's citizens, including those who use, have used, or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to Ray County and the entire state.

271. Defendant' conduct has injuriously affected, and continues to affect, Ray County's property, patrons, employees, and a considerable number of other people within Ray County, and across the state.

272. As a direct and proximate result of Defendants' conduct, and each of them, Plaintiff has sustained and will continue to sustain significant costs to address and attempt to abate this public nuisance in an amount to be determined according to proof at trial. As alleged herein, Defendants' misconduct was and remains willful, wanton, reckless and outrageous given Defendants' evil motives and/or reckless indifference to human life and the rights and safety of Plaintiff and its citizens, resulting in the extensive damages incurred by Plaintiff and justifying an award of punitive damages in a sum to be determined at trial that will serve to punish Defendants to deter Defendants and others from like conduct.

273. Additionally, Ray County requests an order providing for abatement of the public nuisance and enjoining Defendants from such future violations. compensatory damages for the inconvenience and discomfort caused by and continuing to be caused by Defendants as well as reasonable costs for abatement, all in an amount according to proof at trial.

**COUNT II**

**Negligence**

**(Against All Defendants)**

274. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

275. Missouri recognizes a legal duty where the foreseeability of harm is such that harm may result if due care is not exercised. In any action for negligence, the plaintiff must establish the existence of a duty on the part of the defendant to protect the plaintiff from injury, failure of defendant to perform the duty, and that the plaintiff's injury was proximately caused by that failure.

276. At all times mentioned herein, Defendants were under a duty to exercise reasonable care in the manufacturing, marketing, and distribution of their opioid products to ensure that the use of their products did not result in avoidable injuries.

277. Each Defendant owed a duty of care to Plaintiff, including but not limited to, taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

278. In violation of this duty, Defendants, and each of them, failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids by misrepresenting the risks and benefits associated with opioids and by distributing and prescribing dangerous quantities of opioids.

279. Each of the Manufacturer Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was negligible, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies were so efficacious as to virtually negate concerns about addiction, falsely claiming that doctors and patients could increase opioid doses without significant added risk, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life without

posing significant additional risks. Each of these misrepresentations made by Defendants violated a duty of care to Ray County.

280. Each of the Manufacturer Defendants, each of the Distributor Defendants and each of the Pharmacy-Distributor Defendants also owed a duty to report suspicious sales, to not fill suspicious orders; and/or to abide by any government agreements entered into regarding the same and to comply with state regulations. Each of these Defendants breached its duty by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances or by failing to report such suspicious orders to the appropriate regulators.

281. These Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

282. The Distributor Defendants and the Pharmacy-Distributor Defendants negligently distributed suspiciously large quantities of potent opioids and failed to report such distributions. As such, the Distributor Defendants and the Pharmacy-Distributor Defendants violated their duty of care by moving these highly addictive products into Ray County in such quantities, facilitating misuse and abuse of opioids.

283. Plaintiff is not asserting a cause of action under the federal Controlled Substances Act or any other federal controlled substances laws, including—*inter alia*—federal statutes and regulations regarding opioid promotion, opioid manufacturing, opioid distribution, and/or opioid prescribing or dispensing practices.

284. As a direct and proximate result of Defendants' conduct, Plaintiff's citizens have suffered from physical and mental injuries, including death, at Plaintiff's expense. The full extent of the destruction caused by the misrepresentations of these drugs has not yet been quantified because the loss of human life, the resources devoted to administering and trying to save those lives, and the costs incurred by Plaintiff are far reaching.

285. As a direct and proximate result of Defendants' conduct, and each of them, Plaintiff has sustained and will continue to sustain significant costs in an amount to be

determined according to proof at trial.

286. Because Defendants' misconduct as described in this Petition was and remains willful, wanton, reckless and outrageous given Defendants' evil motive and/or reckless indifference to the rights and safety of Plaintiff and its citizenry, Plaintiff is entitled to an award of punitive damages in a sum to be determined at trial that will serve to punish Defendants and to deter Defendants and others from like conduct.

287. As alleged herein, Defendants acted with reckless indifference to human life, including Ray County's citizens, resulting in the extensive damages incurred by Plaintiff and justifying an award of punitive damages.

**COUNT III**

**Negligence Per Se**

**(Against All Defendants)**

288. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

289. At all times mentioned herein, Defendants were under a duty to exercise due care in the manufacturing, marketing, and distribution of their opioids.

290. Missouri law mandates that the Defendants implement effective controls and procedures in their supply chains to guard against theft, diversion, and the abuse of prescription opioids.

291. Missouri Code of State Regulations, 20 CSR 2220-5, *et seq.*, governs the State Board of Pharmacy and statutory requirements for dispensing medication.

292. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(I) requires wholesale drug distributors to establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.

293. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M) requires

wholesale drug distributors to establish written policies and procedures for identifying, recording, and reporting losses or thefts and for correcting errors and inaccuracies in inventory.

294. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M)(5) requires wholesale drug distributors to report suspicions of diversion or theft.

295. Missouri Code of State Regulations, 20 CSR 2220-5.030(3)(M)(5),(7) requires that any suspected criminal activity or diversion be reported.

296. Missouri Code of State Regulations, 20 CSR 2220-5.060 requires wholesale drug and pharmacy distributors to report the distribution of opioid substances.

297. In violation of the above regulations, Defendants failed to adequately design and operate a system to detect, halt, and/or report suspicious orders of prescription opioids.

298. Defendants negligently disseminated massive quantities of prescription opioids into Ray County. Defendants' conduct, actions, and failure to act moved once-legal prescription drugs to unlawful channels of distribution or use.

299. As a direct and proximate result of Defendants' conduct, actions, and failure to act, Ray County has been inundated with an illegal opioid market, which in turn, created substantial addiction problems leading to numerous deaths and other injuries, the costs of which Plaintiff has born, resulting in significant economic damages.

300. Defendants negligently distributed enormous quantities of opioids into the illegal drug market, especially acting as a supplier to illegal drug dealers and permitting opioids to be trafficked and sold in Ray County.

301. Defendants' actions were a substantial factor in making opioids widely available and widely used by the citizens of Ray County. Defendants' actions were a substantial factor in doctors and patients inaccurately assessing the risks and benefits of opioids for the long-term treatment of chronic pain. Without Defendants' actions, opioid use would not have been so widespread and the significant public health hazard of opioid abuse and addiction that exists could have been averted.

302. Defendants knowingly, intentionally, recklessly, and/or negligently disseminated prescription opioids without effective controls and procedures to guard against theft, diversion, and/or abuse of prescription opioids.

303. Defendants' nuisance-causing activities include, but are not limited to, failing to implement effective controls and procedures in their supply chains to guard against theft, diversion, and misuse of prescription opioids, as well as failing to adequately design and operate a system to detect, halt, and/or report suspicious orders of prescription opioids.

304. As a direct and proximate result of Defendants' conduct, Plaintiff's citizens have suffered from physical and mental injuries, including death, at Plaintiff's expense. The full extent of the destruction caused by the misrepresentations of these drugs has not yet been quantified because the loss of human life, the resources devoted to administering and trying to save those lives, and the costs incurred by Plaintiff are far reaching and ongoing.

305. As a direct and proximate result of Defendants' conduct, and each of them, Plaintiff has sustained and will continue to sustain significant costs in an amount to be determined according to proof at trial.

306. Because Defendants' misconduct as described in this Petition was and remains willful, wanton, reckless and outrageous given Defendants' evil motive and/or reckless indifference to the rights and safety of Plaintiff and its citizenry, Plaintiff is entitled to an award of punitive damages in a sum to be determined at trial that will serve to punish Defendants and to deter Defendants and others from like conduct. Indeed, Defendants' misconduct is particularly reprehensible since—in creating, facilitating and/or failing to abate the opioid epidemic in Plaintiff's community—Defendants intentionally performed acts in violation of their legal duties to Plaintiff and/or intentionally failed to perform acts which Defendants had legal duties to perform. Moreover, Defendants' engaged and continue to engage in this misconduct despite knowing or having reason to know of facts

which would lead a reasonable person to realize that such misconduct not only created and continues to create an unreasonable risk of harm, but that Defendants' engaged in this misconduct despite their full realization of the high degree of probability of resulting, substantial harm.

#### **COUNT IV**

##### **Unjust Enrichment**

###### **(Against All Defendants)**

307. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

308. A claim for unjust enrichment in Missouri requires the defendant to be enriched by the receipt of a benefit; that the enrichment be at the expense of the plaintiff; and that it would be unjust to allow the defendant to retain the benefit.

309. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

310. Rather than prevent or mitigate the wide proliferation of opioids into Ray County, each Defendant, instead, chose to place its monetary interests first and each Defendant profited from prescription opioids sold in Ray County.

311. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it or he manufactured or distributed, again choosing, instead, to place its or his monetary interests first.

312. Each Defendant, therefore, received a benefit from the sale, distribution, or prescription of prescription opioids to and in Ray County, and these Defendants have been unjustly enriched at the expense of Ray County.

313. As a result, Ray County is entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

## **COUNT V**

### **Negligent Misrepresentation**

#### **(Against the Manufacturer Defendants)**

314. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

315. At all relevant times mentioned herein, Defendants made many misrepresentations to doctors, patients, and the public in their advertising which, as set forth above, was misbranded, misleading, and contrary to the prescription label.

316. The Manufacturer Defendants are liable for negligent misrepresentation because they supplied information in the course of their business to patients, including those in Ray County. Because the representatives referred to in this Petition were employed or were supplied by the Manufacturer Defendants, they had a duty to exercise reasonable and ordinary care and skill, in accordance with applicable standards of conduct, to adequately warn the medical profession about the risks of addiction from the use of opioid products and to not over-promote and over-market opioid products so as to nullify, cancel out, and render meaningless any written warnings about addiction, however inadequate, regarding the risk of addiction from the use of opioid products.

317. The Manufacturer Defendants intentionally breached their duty to exercise reasonable and ordinary care by negligently misrepresenting the true risks of addiction from the use of opioid products to the medical profession. Moreover, the Manufacturer Defendants so over-promoted the products to nullify, cancel out and render meaningless any warnings in the labels about any addiction risk due to the Manufacturer Defendants' marketing, sales and promotional efforts that were designed to stimulate the use of opioid products for patients who either should not have been using those drugs, or should have used them only as a last resort before other means were used or other less addictive and dangerous drugs were prescribed.

318. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Ray County has suffered and will continue to suffer harm, and is entitled to damages in an amount to be determined at trial.

319. Because Defendants' misconduct as described in this Petition was and remains willful, wanton, reckless and outrageous given Defendants' evil motive and/or reckless indifference to the rights and safety of Plaintiff and its citizenry, Plaintiff is entitled to an award of punitive damages in a sum to be determined at trial that will serve to punish Defendants and to deter Defendants and others from like conduct. Indeed, Defendants' misconduct is particularly reprehensible since—in creating, facilitating and/or failing to abate the opioid epidemic in Plaintiff's community—Defendants intentionally performed acts in violation of their legal duties to Plaintiff and/or intentionally failed to perform acts which Defendants had legal duties to perform. Moreover, Defendants' engaged and continue to engage in this misconduct despite knowing or having reason to know of facts which would lead a reasonable person to realize that such misconduct not only created and continues to create an unreasonable risk of harm, but that Defendants' engaged in this misconduct despite their full realization of the high degree of probability of resulting, substantial harm.

## **COUNT VI**

### **Fraud in the Omission (Against All Defendants)**

320. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

321. Defendants, having undertaken the manufacturing, marketing, distributing, monitoring, reporting, and promotion of their various opioid products as previously described in this Petition, owed a duty to provide accurate and complete information regarding these products.

322. Through the use of Front Groups, KOLs, and advertising to treating and prescribing physicians, Defendants omitted material facts about the lack of evidence regarding the safety and efficacy for opioid use in the long-term treatment of chronic pain.

323. Defendants, acting in concert and/or in a conspiracy with each other, deceptively misrepresented the true nature of their opioid products with a mutual intent and purpose to deceive patients and prescribing physicians about the safety and efficacy of opioids. These deceptive omissions caused or contributed to cause damages incurred by Plaintiff.

324. Defendants marketed, advertised, and distributed, through the use of KOLs and organizations which they funded, omissions that were materially relied upon by patients and prescribing healthcare providers as previously described in this Petition.

325. Plaintiff has had to expend funds for criminal investigation, judicial, public safety, and health-related costs as a direct result of Defendants' fraudulent conduct.

326. Defendants' conduct in illegally distributing and/or selling prescription opioids or conduct allowing opioids to be distributed and/or sold illegally is ongoing and continues to harm Plaintiff and continues to create an ongoing public nuisance.

327. Defendants' conduct in marketing, distributing, selling, and filling prescription opioids which Defendants know, or reasonably should know, will be diverted for non-legitimate use and thereby cause significant injury and death to the citizens of Ray County at Plaintiff's expense. Additionally, the prevalence and widespread availability of diverted opioids creates a climate of fear throughout Ray County, which Plaintiff must combat through enhanced law enforcement measures at significant expense to Plaintiff. Defendants' conduct, therefore, has made it increasingly easy for the diversion of prescription opioids, which has harmed and continues to harm the public health and safety of Ray County's citizens while also causing Ray County and its citizens to incur significant economic harm.

328. As a direct and proximate result of Defendants' conduct, Plaintiff's citizens

have suffered from physical and mental injuries, including death, at Plaintiff's expense. The full extent of the destruction caused by Defendants' wrongful conduct has not yet been quantified because the loss of human life, the resources devoted to administering and trying to save those lives, and the costs incurred by Plaintiff are far reaching and ongoing.

329. As a direct and proximate result of Defendants' conduct, and each of them, Plaintiff has sustained and will continue to sustain significant costs in an amount to be determined according to proof at trial.

330. Because Defendants' misconduct as described in this complaint/petition was and remains willful, wanton, reckless and outrageous given Defendants' evil motive and/or reckless indifference to the rights and safety of Plaintiff and its citizenry, Plaintiff is entitled to an award of punitive damages in a sum to be determined at trial that will serve to punish Defendants and to deter Defendants and others from like conduct.

### **COUNT VII**

#### **Fraud**

##### **(Against All Defendants)**

331. Ray County re-alleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Petition as though fully alleged in this Cause of Action.

332. At all times relevant to this action, Defendants acted in concert with a common intent and purpose to deceive patients and physicians, including those within Ray County. Defendants' actions and deceptive conduct caused, contributed to, and continues to cause or contribute to Plaintiff's damages.

333. Defendants marketed, advertised, and distributed, through the use of KOLs and organizations which they funded, deceptive and false statements and misrepresentations regarding the long-term use and benefits of prescription opioids which were materially relied upon by patients and physicians, as previously described in this Petition.

334. Defendants, as the manufacturers, marketers, distributors, and promoters of opioids, owed a duty to provide accurate and complete information regarding their opioid products.

335. Defendants' promotional, marketing, and distribution plan, developed in concert with one another, had the goal of increasing the volume of opioid products present in Ray County. As previously described herein, Defendants cultivated an image that the use of opioid products was proper for the long-term treatment of chronic pain and that the opioid products were safe, non-addictive, and would not interfere with everyday life.

336. Defendants acted in concert to fund, direct, and guide KOLs and Front Groups to tout the false benefits of opioids and downplay its harsh side effects, specifically, addiction and death, which patients and healthcare providers in Ray County reasonably relied on to their detriment.

337. As a direct and proximate result of Defendants' conduct, Plaintiff's citizens have suffered from physical and mental injuries, including death, at Plaintiff's expense. The full extent of the destruction caused by Defendants' wrongful conduct has not yet been quantified because the loss of human life, the resources devoted to administering and trying to save those lives, and the costs incurred by Plaintiff are far reaching and ongoing.

338. As a direct and proximate result of Defendants' conduct, and each of them, Plaintiff has sustained and will continue to sustain significant costs in an amount to be determined according to proof at trial.

339. Because Defendants' misconduct as described in this complaint/petition was and remains willful, wanton, reckless and outrageous given Defendants' evil motive and/or reckless indifference to the rights and safety of Plaintiff and its citizenry, Plaintiff is entitled to an award of punitive damages.

## **VI. PRAYER FOR RELIEF**

Ray County prays that the Court issue:

1. An Order declaring that Defendants have created a public nuisance;

2. An Order enjoining Defendants from performing any further acts which constitute a public nuisance;
3. An Order requiring Defendants to abate the public nuisance that they created;
4. An Order that Defendants are negligent under Missouri law;
5. An Order that Defendants have been unjustly enriched at Ray County's expense under Missouri law;
6. An Order that Ray County is entitled to recover all measure of damages permissible under the statutes identified herein and under Missouri common law, in an amount to be proven at trial;
7. An Order that judgment be entered against Defendants, jointly and severally, in favor of Ray County;
8. An Order that Ray County is entitled to attorney's fees and costs pursuant to any applicable provision of law;
9. Compensatory damages in the sum to be determined at trial;
10. Punitive damages against Defendants in sums to be proven at trial that will serve to punish Defendants and to deter Defendants and others from like conduct; and
11. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

**VII. JURY TRIAL DEMAND**

340. Ray County demands a trial by jury on all claims and of all issues so triable.

DATED: October 22, 2019

Respectfully submitted,

**EDGAR LAW FIRM LLC**

*/s/ John F. Edgar*

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